Filed Pursuant to Rule 424(b)(4)
Registration No. 333-259250

PROSPECTUS

12,500,000 Shares

Common Stock

This is the initial public offering of shares of common stock of Cue Health Inc.

We are offering 12,500,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is 16.00. Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "HLTH."

We are an emerging growth company under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves a high degree of risk. See the section titled "Risk Factors" beginning on page 26.

	Per Share	Total
Initial public offering price	$16.00	$200,000,000
Underwriting discounts and commissions(1)	$ 1.12	$ 14,000,000
Proceeds, before expenses, to us	$14.88	$186,000,000

(1) See the section titled "Underwriting" for additional disclosure regarding the underwriting discounts and commissions and estimated offering expenses.

We have granted the underwriters the right to purchase up to an additional 1,875,000 shares of common stock from us at the public offering price less underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on or about September 28, 2021.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Joint Book-Running Managers

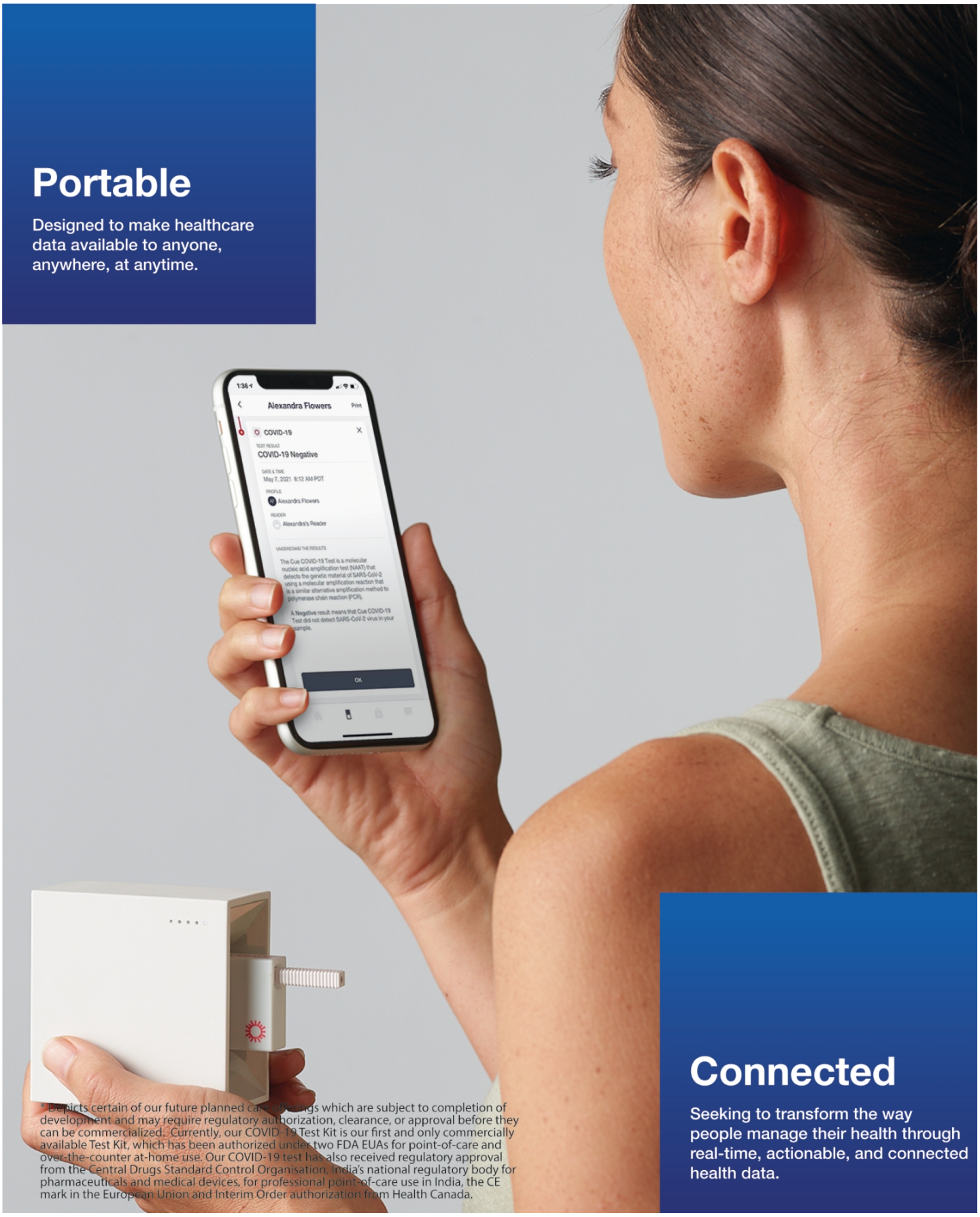
Goldman Sachs & Co. LLC **Morgan Stanley** **Cowen**

Lead Manager

BTIG

September 23, 2021

Our mission is to enable **personalized, proactive,** and **informed healthcare** that empowers people to live their healthiest lives.



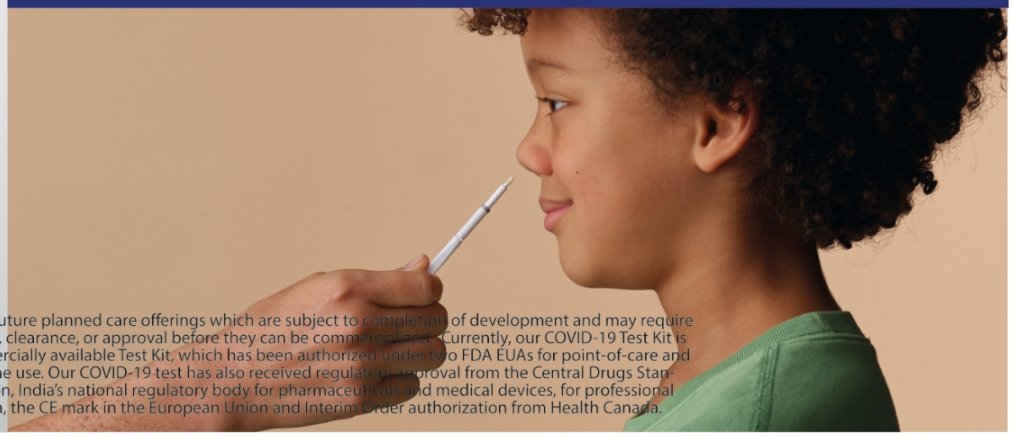
* Depicts certain of our future planned cartridges which are subject to completion of development and may require regulatory authorization, clearance, or approval before they can be commercialized. Currently, our COVID-19 Test Kit is our first and only commercially available Test Kit, which has been authorized under two FDA EUAs for point-of-care and over-the-counter at-home use. Our COVID-19 test has also received regulatory approval from the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India, the CE mark in the European Union and Interim Order authorization from Health Canada.

Fast & Accurate

Lab-quality diagnostics anywhere in minutes to make faster and more informed healthcare decisions.

Intuitive

Designed to deliver a superior user experience in any setting; one that is fully guided, easy to use, and puts the consumer in control of their health data.



* Depicts certain of our future planned care offerings which are subject to completion of development and may require regulatory authorization, clearance, or approval before they can be commercialized. Currently, our COVID-19 Test Kit is our first and only commercially available Test Kit, which has been authorized under two FDA EUAs for point-of-care and over-the-counter at-home use. Our COVID-19 test has also received regulatory approval from the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India, the CE mark in the European Union and Interim Order authorization from Health Canada.

We are helping **pioneer a healthcare digital transformation, beginning with diagnostics.**

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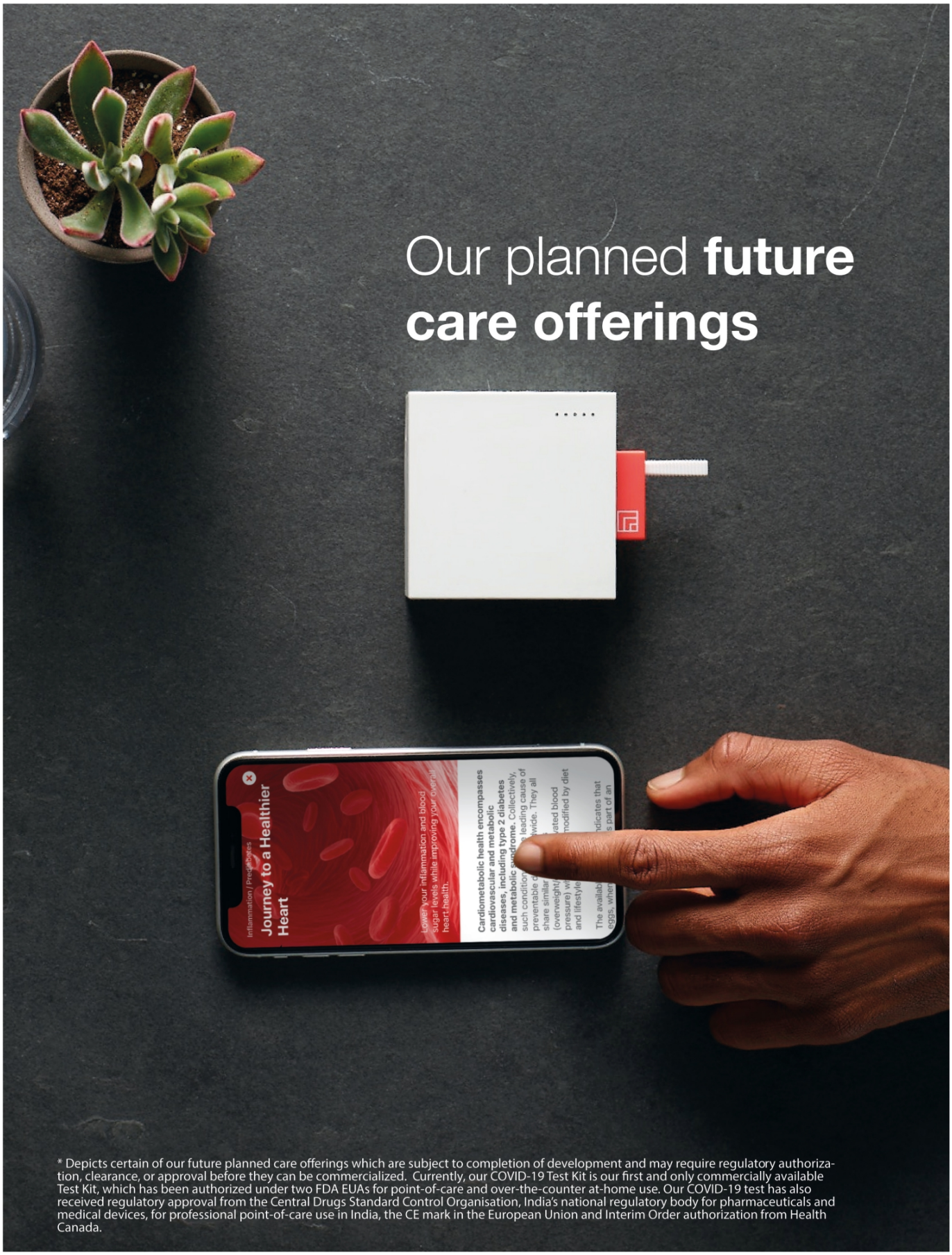

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Neither we nor the underwriters have authorized anyone to provide you with any information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

Through and including October 18, 2021 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." In this prospectus, unless otherwise indicated or the context otherwise requires, references to "Cue," "Cue Health," "we," "us," "our" and similar references refer to Cue Health Inc. and, as the context requires, our predecessor entity, Ruubix, that changed its name to Cue Inc. in 2014 and subsequently merged with Cue Health Inc. in 2017.

Overview

Reinventing How We Interact with Our Health

We are a health technology company, and our mission is to enable personalized, proactive and informed healthcare that empowers people to live their healthiest lives. Digital transformation has revolutionized nearly every industry except healthcare to create new, consumer-first experiences that are both personalized and empowering. We seek to usher in a new era in healthcare, what we call Healthcare 2.0, to transform how acute and chronic conditions are diagnosed and managed.

We believe the current healthcare system is challenged. Care delivery can often be uncontextualized and disconnected in an increasingly personalized and connected world. The vast majority of healthcare delivery still relies on in-person encounters at centralized locations while consumers and caregivers may often be forced to make important health decisions without complete or real-time information. The first step in many healthcare journeys is often diagnosis, a critical part of the healthcare value chain. Despite being a key basis for care decisions, we believe current diagnostic solutions are suboptimal because they are not timely, convenient, or connected to care delivery. The COVID-19 pandemic exposed the shortcomings of our healthcare system and of diagnostics in particular. A centralized and rigid testing infrastructure, the reliance on in-person encounters, and the lack of timely information illustrate how current diagnostic solutions are not built for modern care delivery to hundreds of millions of people. We believe consumers want the same tech-enabled convenient, connected, and customized experiences that have transformed their daily lives to transform their care journeys.

We are now witnessing what we believe is the beginning of a transformational shift as consumers take control of their own health. In industry after industry, disruptors are using technology to transform the consumer experience. From the way we consume content to the way we travel, we believe consumers and organizations are increasingly looking for a simple, convenient and digital first approach. We further believe that healthcare is finally ripe for a digital transformation and that it will begin with diagnostics, since approximately 70% of all clinical decisions are made utilizing diagnostic data.

We are helping pioneer this healthcare digital transformation, beginning with diagnostics. We started from consumer-centric principles and designed our proprietary platform, the Cue Integrated Care Platform, with a relentless focus on user experience, convenience, and accuracy. The Cue Integrated Care Platform consists of hardware and software components: (1) our revolutionary Cue Health Monitoring System, made up of a portable, durable and reusable reader, or Cue Reader, a single-use test cartridge, or Cue Cartridge, and a sample collection wand, or Cue Wand, (2) our Cue Data and Innovation Layer, with cloud-based data and analytics capability, (3) our Cue Virtual Care Delivery Apps, including our consumer-friendly Cue Health App and our Cue Enterprise Dashboard, and (4) our Cue Ecosystem Integrations and Apps, which allow for integrations with third-party applications and sensors.

Our platform has been designed to work seamlessly to deliver and manage health data both within the healthcare system and within the home. Through our application programming interfaces, or APIs, our platform has been engineered so that it can be directly integrated into existing workflows and on-demand services, such as telemedicine, e-prescription services, and electronic medical record, or EMR, systems. For example, we implemented an integration with one of the U.S.'s leading EMR systems on behalf of one of our customers, a leading healthcare system, to enable a seamless workflow from test ordering to test result, with our mobile app and the Cue Health Monitoring System. But beyond designing our platform to be able to integrate within the traditional healthcare system, we have built our platform to enable fast, frequent, lab-quality diagnostics by anyone, anywhere, intended to facilitate a new continuous care model of personalized and contextualized healthcare. Our first commercially available diagnostic test for use with our Cue Health Monitoring System, our COVID-19 Test Kit, which has been

authorized by two Emergency Use Authorizations, or EUAs, from the U.S. Food & Drug Administration, or the FDA, for point-of-care and over-the-counter and at-home use, is an example of this. Users can run a COVID-19 test anywhere using the Cue Reader and a COVID-19 Test Kit, and have lab-quality test results delivered digitally to the user's mobile device in about 20 minutes. While our COVID-19 Test Kit is our only commercially available Test Kit and our future tests remain subject to technical development, clinical studies and regulatory authorization, clearance or approval, we have five additional Test Kits in late-stage technical development (influenza A/B, or flu, respiratory syncytial virus, or RSV, fertility, pregnancy and inflammation) for which we expect to begin submitting for FDA authorization or clearance in the second half of 2022. Based on the working prototypes we have developed for technical development, as well as other Test Kits we currently have in development, and the clinical and other development work we have performed to date with respect to our Test Kits in development, we expect that all of our Test Kits currently in development will work within our Cue Health Monitoring System in a manner similar to our COVID-19 Test Kit and will be able to be utilized with our Cue Health App and the Cue Enterprise Dashboard and be capable of being integrated with existing workflows, including EMRs, and with other planned on-demand services. We believe our model, driven by our platform, will empower our users to actively manage their health, which we believe will result in improved health outcomes and a more resilient, connected, and efficient healthcare ecosystem for all. We further believe that our platform positions us to be at the center of the broader healthcare ecosystem as it continues to undergo a massive virtual and digital shift. Through our connected diagnostic solution, we seek to enable the shift of care to virtual settings, while also connecting the physical care paradigm to the new digital ecosystem.

As the COVID-19 pandemic was closing the global economy and filling hospitals in the first quarter of 2020, we rapidly focused our team on developing a COVID-19 Test Kit and did so in a matter of a few months, building on a decade of research and development on our adaptive and flexible system. Our COVID-19 test (consisting of our Cue Reader and COVID-19 Test Kit) has been validated via an independent clinical study conducted by researchers at the Mayo Clinic that demonstrated our COVID-19 test has 97.8% concordance with tests performed by central labs using reverse transcription polymerase chain reaction, or RT-PCR technology, the current "gold standard" for central lab testing. Our platform has been designed to uniquely offer fast results and ease-of-use combined with the high-quality results of central lab technology, all in a device that fits in the palm of your hand.

Our first commercially available diagnostic test for use with our Cue Health Monitoring System is our COVID-19 Test Kit for ribonucleic acid, or RNA, of SARS-CoV-2, the virus that causes COVID-19. In June 2020, the FDA granted an EUA for our molecular COVID-19 test for point-of-care use under the supervision of qualified medical personnel. In March 2021, the FDA granted us an additional EUA for over-the-counter and at-home use of our COVID-19 test without a prescription. Our COVID-19 test is authorized for use by both symptomatic and asymptomatic individuals, and by adults and children aged two and older with adult assistance. While commercial sales of our COVID-19 Test Kit are authorized pursuant to our two EUAs, we cannot predict how long our EUAs will remain in effect and, to date, we have not obtained any clearances under Section 510(k) of the Federal Food, Drug and Cosmetic Act of 1938, as amended, or 510(k), for our COVID-19 Test Kit, which such clearance would be required to sell our COVID-19 Test Kit in the event that the FDA terminates or revokes our EUAs. In order to be eligible to receive 510(k) clearance from the FDA, we will need to conduct additional clinical studies with larger subject enrollment and more COVID-19 positive tests. We are moving forward on the additional steps we believe are required to enable us to seek 510(k) clearance, and intend to seek 510(k) clearance as soon as feasible once we have completed these steps. See "Business—Our First Product Offering—Cue COVID-19 Test Kit—Regulatory Status of the Cue COVID-19 Test Kit" for additional information regarding what is required for the regulatory clearance process for our COVID-19 Test Kit.

While our Cue COVID-19 Test Kit is our first, and currently only, commercially available test, our vision was always to build a broad platform that would reinvent how we interact with our health. Since our early days, we developed our platform to be able to address the majority of diagnostic tests routinely conducted in clinical laboratories because we believe that users will not only demand a simple, personalized, convenient and connected solution but also a single platform to address their healthcare needs. We are developing solutions to broaden the diagnostic use cases for our platform, such as our five tests we consider to be in late-stage technical development. Our additional planned care offerings include tests in the categories of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. We are also working to expand

the functionality of our platform by adding capabilities which will enable telehealth, e-prescription and the ability to connect to third-party services to facilitate an end-to-end healthcare journey. Our focus is on creating experiences with the user at the center, enabling high satisfaction, measurable health outcomes, and more cost-effective care for the entire ecosystem.

We believe the power of our platform has been demonstrated by our substantial growth, the quality of our customers, the clinical validation of our COVID-19 Test Kit, and the several regulatory authorizations we have received for our COVID-19 Test Kit, including being the first company ever to have a product authorized by the FDA for molecular-based infectious disease testing available over-the-counter for home use. Our platform was trusted by the National Basketball Association, or NBA, to help it perform COVID-19 testing in its highly publicized "Bubble" in the 2020 basketball season. Our products are used by the Mayo Clinic in their hospital network and in their laboratories. In October 2020, we entered into a $480.9 million agreement or the U.S. DoD agreement, with the U.S. Department of Defense, or U.S. DoD, and the U.S. Department of Health and Human Services, or U.S. HHS, to scale up our production and deliver 6,000,000 COVID-19 Test Kits and 30,000 Cue Readers. Our customers also include certain major technology and other enterprises who are providing our solution to their employees for use in their homes as part of return to work initiatives and ongoing employee health benefits. Today our platform is relied upon every day for vital COVID-19 testing across schools, enterprises, nursing homes, hospitals, physicians' offices, dental clinics, sports and other live event venues, federal and state agencies, and other settings around the country as well as by individual end-users testing in their homes. As of August 31, 2021, we had 49 active customers, which includes our largest customer by product volume to date, the U.S. DoD. We define an active customer as an entity that has entered into an agreement with us to purchase the Cue Health Monitoring System or Test Kits in the past 12 months.

Prior to March 31, 2021, we were required, pursuant to the U.S. DoD agreement, to deliver to the U.S. government all of our manufacturing output of COVID-19 Test Kits, subject to limited exceptions. The U.S. DoD agreement initially contemplated a ramp-up in our production to 100,000 COVID-19 Test Kits per day for a seven-day period and final delivery of the required Cue Readers and Cue COVID-19 Test Kits by March 31, 2021. However, the production ramp up target and final product delivery dates were extended by mutual agreement in March 2021 to October 12, 2021, and further extended in September 2021 to December 31, 2021. In April 2021, the U.S. DoD granted us a waiver whereby, effective May 1, 2021, we are permitted to sell up to 50% of our manufacturing output of COVID-19 Test Kits to additional customers. Notwithstanding the waiver granted to us by the U.S. DoD, we are still required under the U.S. DoD agreement to deliver 30,000 Cue Readers, 6,000,000 COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs by December 31, 2021. As of August 31, 2021, we have delivered all of the required Cue Readers and over three and a half million Cue COVID-19 Test Kits pursuant to the U.S. DoD agreement. We are further required to ramp up our production capacity to approximately 100,000 Cue COVID-19 Test Kits per day for a seven-day period by December 31, 2021. As of August 31, 2021, our daily manufacturing capacity was on average over 43,000 COVID-19 Test Kits per day over a seven-day period, with a single day peak of nearly 60,000 COVID-19 Test Kits. We believe that the receipt of our waiver from the U.S. DoD will allow us to more widely commercialize our COVID-19 Test Kit. Since we received the waiver from the U.S. DoD and our second FDA EUA for over-the-counter and at-home testing for our COVID-19 Test Kit, we have been able to add several new enterprise customers and extend our business with existing customers. For example, we have added certain major technology and other enterprises as customers who are providing our solution to their employees for use in their homes as part of return to work initiatives and ongoing employee health benefits. In addition, for the 2021 and 2022 NBA basketball seasons, we have been able to extend our relationship with the NBA to provide our testing solution for use by players, their families, staff and referees, at home and on the road.

We believe our platform will allow us to develop and commercialize new tests quickly and scale rapidly, driven by our flexible technology and our in-house, vertically-integrated and automated manufacturing facilities. Our platform has the potential to perform a variety of different tests by accommodating different sample types, including saliva, blood, urine and swabs, and detecting nucleic acids, small molecules, proteins or cells. Because we developed our manufacturing facilities and processes in tandem with our technology, we were able to scale our production to produce a rate of millions of Test Kits per year using fully automated production pods. A production pod is a free standing, modular environmentally-controlled structure containing an automated test cartridge production line. Additionally, we produce our critical biochemistry in-house, including enzymes, antibodies and primers for our Cue Cartridges. As of August 15, 2021, we were manufacturing Cue Cartridges at a rate equivalent to over 15 million per year and we anticipate growing our manufacturing capacity to a rate equivalent to tens of millions of Cue Cartridges per year by the end of 2021.

We first began generating revenue from product sales in August 2020 following the receipt of our first EUA from the FDA for our COVID-19 test in June 2020. We generated approximately $201.9 million of revenue in the six months ended June 30, 2021, all of which was from product sales. Of that amount, $167.1 million, or approximately 83%, of our product revenue was from public sector entities, substantially all of which was from the U.S. DoD, with the remaining $34.8 million of product revenue generated from other customers (of which a single enterprise customer accounted for $28.9 million). We generated $23.0 million of revenue for the year ended December 31, 2020, of which approximately $15.4 million was from product sales. Of this amount, $8.9 million of product revenue was from public sector entities, substantially all of which was from the U.S. DoD, and the remaining $6.5 million of product revenue was generated from other customers. The U.S. DoD and Henry Schein accounted for approximately 80% of our product revenue in 2020. In 2019, we generated $6.6 million of revenue, none of which was from product sales. After the conclusion of the initial U.S. DoD agreement, we anticipate that the percentage of our revenue derived from non-public sector customers will increase as we continue to ramp up our manufacturing and distribution capabilities and are able to sell more of our products to other customers, including enterprises and healthcare providers. For the six months ended June 30, 2021, our net income was $32.8 million. In 2020 and 2019, we incurred net losses of $47.4 million and $20.6 million, respectively.

Healthcare 1.0

We believe the current healthcare system suffers from centralization, and is disconnected, analog and access-limited. We call the current system Healthcare 1.0. Globally, healthcare has become increasingly complex and we believe continues to suffer from significant fragmentation of care, while costs have continued to expand faster than the growth of the economy. Rising healthcare costs have not necessarily resulted in improved outcomes, as exemplified through the increasing prevalence of chronic conditions in the United States despite the country's approximately $4.0 trillion annual spend, the highest per capita healthcare spend in the world.

Key characteristics of Healthcare 1.0 include:

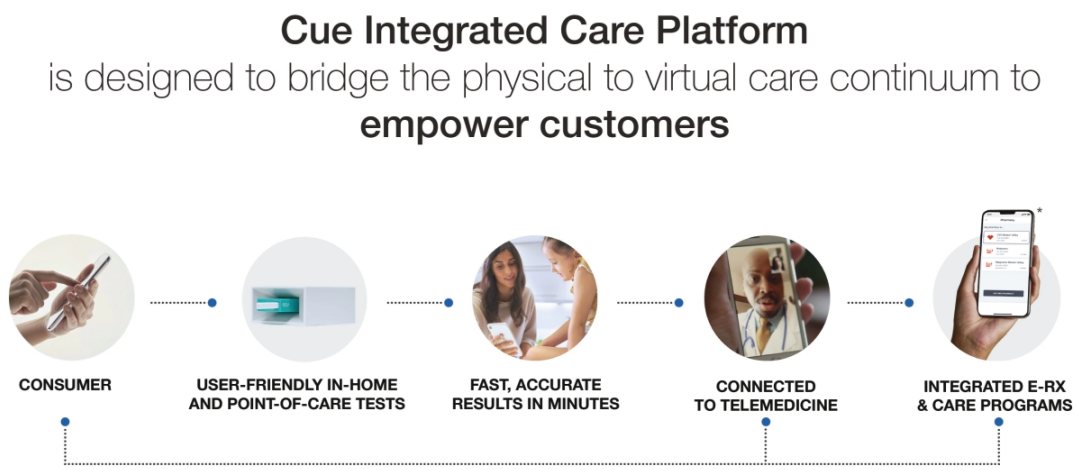
- **Centralized Care Limits Access:** We believe healthcare that is delivered through centralized, physical locations limits access due to the inconvenience and time-consuming nature of visiting hospitals, doctors' offices, and urgent care clinics.
- **The Centralized Diagnostic Testing Framework is Challenged**: In the United States today, there are hundreds of thousands of diagnostic access points to serve hundreds of millions of people. The lack of real-time, convenient, and readily accessible diagnostic solutions is a direct result of the legacy central lab testing model.

- **Legacy Infrastructure Is Not Built for Virtual Care**: The current centralized diagnostic and care infrastructure is even less well suited for the growing virtual care delivery model. For care to truly be virtual, we believe patients need the ability to obtain a diagnostic result from anywhere and at any time, rather than from a central laboratory with high latency.
- **Lack of Capabilities to Identify Health Threats**: We believe the disconnected and high-latency diagnostic system is not able to deliver the information that public health agencies and other healthcare providers need to identify, mitigate and monitor outbreaks of highly contagious diseases, such as COVID-19 or influenza.

  Further, Healthcare 1.0 does not meet the evolving needs of healthcare consumers who we believe are demanding:

  - control over how they manage their acute and chronic conditions as well as their overall health;
  - access to actionable clinical insights;
  - affordable and transparent pricing; and
  - customer-centric user experiences that connect the entire care journey.

Healthcare 2.0



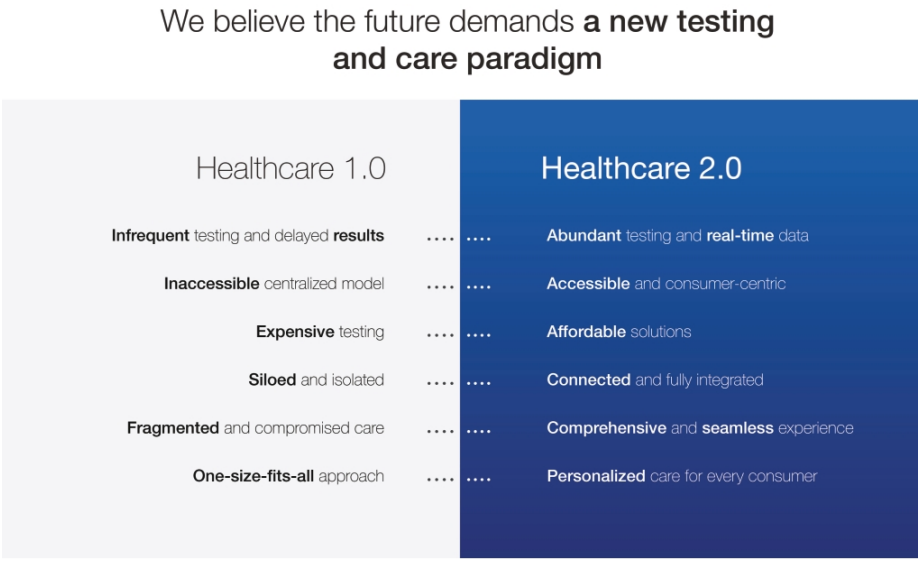
* Depicts future product developments.

Digital transformation has revolutionized nearly every industry, except for healthcare, to create new, consumer-first experiences that are both personalized and empowering. We believe a new era in healthcare is beginning, Healthcare 2.0. We envision that Healthcare 2.0 will be a connected and distributed care ecosystem with seamless coordination across the physical and virtual care continuums and we believe that abundant and timely testing and real-time data will be at the center of personalized and informed care. As diagnostics-led care moves away from centralized, geographically defined settings and toward distributed, virtual modalities, we believe a connected diagnostics platform is needed to bring testing to the user, when and where they need it most.

We believe the healthcare paradigm is shifting and that we are well positioned to be at its center.

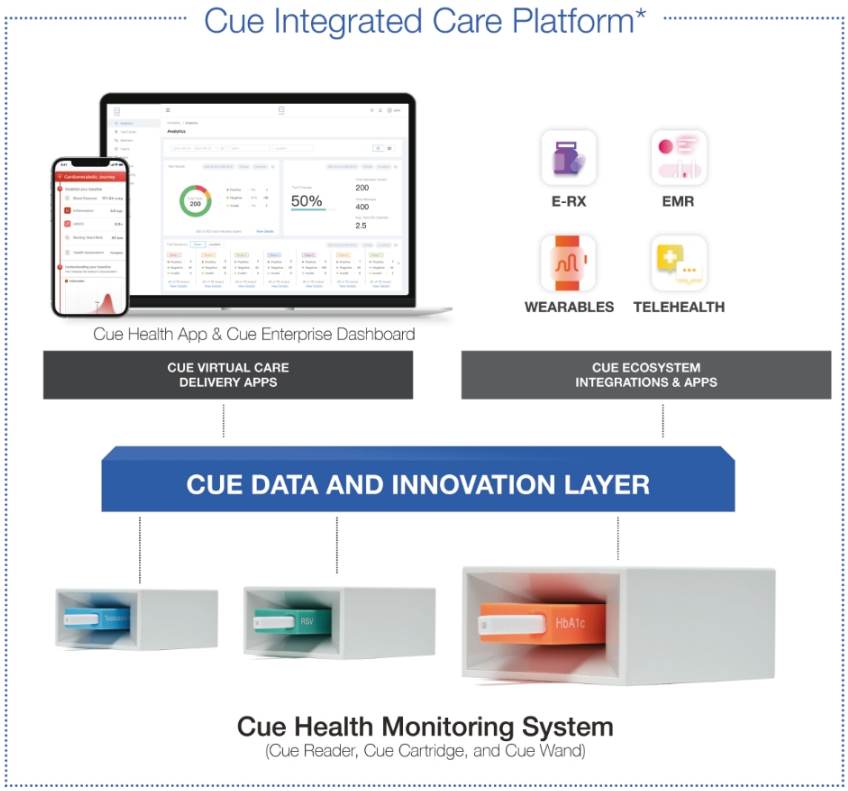
- **Healthcare is Shifting to Consumer-Focused Care and Delivery**: Across multiple industries, new disruptors have used technology to transform the consumer experience. We believe a paradigm shift is occurring in healthcare as consumers are both increasingly informed and focused on the user experience. We believe this shift will become one of the most important factors that shapes the next decade of healthcare.
- **Diagnostics is at the Center of Healthcare 2.0**: We believe diagnostic data is the key to unlocking the full potential of personalized and virtually delivered care. Without an at-home testing solution, we believe telehealth solutions will still be burdened by long turnaround times, and require individuals to visit, or mail samples to, centralized testing laboratories.

- **We are well positioned to be at the Center of Healthcare 2.0**: We believe we have the potential to become the new standard of care in diagnostics, with the ability to bridge the physical to virtual care continuum and benefit everyone by keeping people healthy and productive. Just as monitoring combined with data-driven insights helps people with chronic conditions live healthier lives, we believe our platform will transform the way people manage their health through real-time, actionable and connected health data.



Our Solution – The Cue Integrated Care Platform

Our Cue Integrated Care Platform is designed to harness the power of the cloud and provide consumers and enterprises with real-time access to their data and the broader healthcare ecosystem as part of our planned end-to-end solution.



* Depicts future product developments.

Development of the Cue Integrated Care Platform is guided by our focus on the user, whether that be a clinician in a provider office or an individual at home, with a simple goal of enabling individuals and clinicians to have reliable information at their fingertips to make faster and more informed healthcare decisions. We believe we will be able to transform disease prevention and detection globally by making important healthcare data available to anyone, anywhere, at any time. Our system is designed to put consumers in control of their information and place diagnostic information at the center of care, where it belongs.

For consumers, we expect our platform will eliminate the friction of taking a test and communicating the results to providers. We believe increasing consumer testing at home will lead to better outcomes. By making our platform widely available to consumers over-the-counter for use anywhere and at any time, we aim to redefine the care workflow such that over time we believe our platform will become the standard of care.

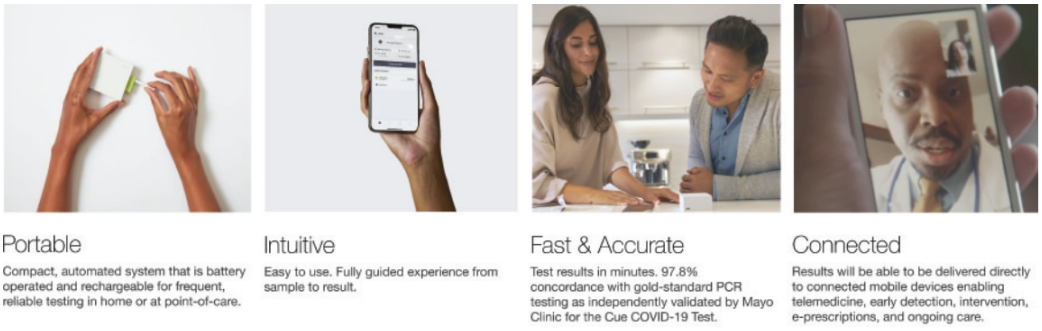
Cue Reader | Cue Cartridge | Cue Wand | Cue Health App | Cue Enterprise Dashboard

Cue Health Monitoring System

Our Cue Health Monitoring System is designed to deliver a broad menu of tests through one system, enabling two major testing modalities, nucleic acid amplification tests, or NAAT, and immunoassays, in one device. Our system is designed to handle different sample types, including saliva, blood, urine and swabs, and can detect nucleic acids, small molecules, proteins and cells. We believe this flexible design will enable us to address many of the diagnostic tests conducted in clinical laboratories, such as tests addressing indications in respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management.

Our Cue Health Monitoring System is comprised of the following elements:

- *Cue Reader:* The Cue Reader is an elegantly designed, automated analyzer of test results and is used with Cue Test Kits and the Cue Health App. The Cue Reader runs the Cue Cartridge and communicates the result of the test digitally via Bluetooth to the Cue Health App.
- *Cue Test Kit:* Each Cue Test Kit is comprised of a Cue Cartridge and a Cue Wand.
  - *Cue Cartridge:* Our sample-specific, single-use cartridges are designed to handle different chemistries, which allows us to create a broad menu of tests. Cue Cartridges are designed to be seamlessly inserted into the Cue Reader.
  - *Cue Wand:* Cue Wands are single-use and sterile sample collection devices that are designed to be universally compatible with the Cue Cartridges. The Cue Wand is designed to permit collection of multiple sample types, including saliva, blood, urine and swabs, with only minor modifications.



Cue Data and Innovation Layer

Our cloud-native Cue Data and Innovation Layer stores and curates the data from our Cue Health Monitoring System and provides a secure environment for users to access current and historical health data. Our Data and Innovation Layer has the ability to collate unstructured and structured data from a wide variety of data sources, which we believe will give us the ability in the future to store and analyze more holistic sets of health data, including from other testing modalities and wearables. The Cue Integrated Care Platform was built with data security and regulatory compliance, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, at its core.

The Cue Data and Innovation Layer provides the foundation for our Cue Virtual Care Delivery Apps and has enabled the development of our Cue Ecosystem Integrations and Apps. The Cue Data and Innovation Layer currently contains an API that allows for the data from tests performed on the Cue Health Monitoring System to be received, stored, and retrieved by the end user. For enterprises deploying the Cue Enterprise Dashboard, the Cue Data and Innovation Layer enables the creation of a network of users affiliated by roles with the enterprise. Within this network of users, the Cue Data and Innovation Layer provides the engine behind test analytics, creation of groups, scheduling and compliance, reporting, and enterprise-specific privacy policy management. The Cue Data and Innovation Layer powers integration with EMR providers.

Cue Virtual Care Delivery Apps

- *Cue Health App:* Our mobile app creates a secure interface between the user and their health data. For consumers, it allows a single point of entry for their health data; for healthcare professionals, it is designed to provide a unified platform for managing patient histories and, in the future, is expected to allow for

telemedicine and e-prescription services. By connecting the diagnostic test results with interventions and outcomes, we believe the Cue Health App will allow users to be more engaged and satisfied with their healthcare experience, which can ultimately drive better outcomes for users. To run a Test Kit on the Cue Reader, a user will need to download and utilize the Cue Health App. As of August 31, 2021, through our 49 active customers, over 45,000 unique accounts have used the Cue Health App to run our COVID-19 Test Kit. These unique accounts include both organizations and individuals who may take tests episodically, healthcare providers running a large number of tests for multiple patients, and enterprises running a large number of tests for their entire organization, as established by the customer on a customer-by-customer basis.

- *Cue Enterprise Dashboard:* Our dashboard is designed to allow enterprises, payors, healthcare providers and public health entities to manage population health at the organizational level and has the potential to track the efficacy of various population health programs. Accessible online, the Cue Enterprise Dashboard has the potential to help organizations manage a patient's journey from onboarding to scheduling, care management and inventory management. The Cue Enterprise Dashboard was built with a focus on user experience, simplifying the sharing of communications, such as results, records, and histories with patients and across providers and streamlining reporting requirements. Powered by our analytics engine and role-based access capabilities, it is designed to provide chief medical officers, environmental health and safety officials, and benefits managers with insight into their organization's population health, helping to facilitate efficient decision making. As of August 31, 2021, we had 60 active public sector, enterprise and provider accounts on the Cue Enterprise Dashboard. An account on the Cue Enterprise Dashboard is considered to be active if the customer has signed into their account and utilized the programs within the last six months. A customer may have more than one active account on the Cue Enterprise Dashboard.

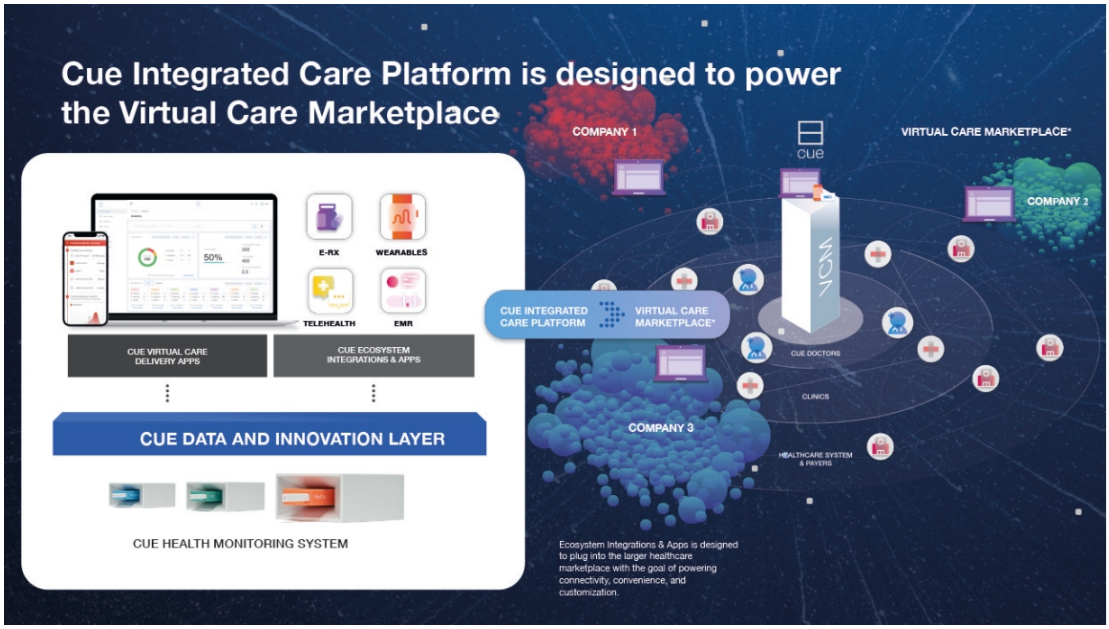
Cue Ecosystem Integrations and Apps

We believe that placing our APIs at the core of our integrated care platform will enable us to become foundational within Healthcare 2.0. Our Cue Data and Innovation Layer is designed to be able to securely connect with on-demand services, such as telemedicine and e-prescription services, which we believe will enable a truly digital and seamless user experience. In the future, we plan on enhancing our platform to enable third-party application development and offerings that complement our solutions.

In addition, our ability to integrate with anchor EMR systems, such as Epic Systems Corporation, or Epic, allows our customers to integrate our platform with their existing systems, creating an agile and responsive workflow for patient monitoring for ongoing care, better intelligence and reporting, and more efficient provider-level health management.

The Cue Virtual Care Marketplace

Our current customers can be categorized as both care consumers, including enterprises and the employees that comprise them, and care providers, including doctor's offices, healthcare systems and urgent care clinics. We believe that as both care consumers and care providers take advantage of our Cue Integrated Care Platform to better diagnose and manage health, our networked Virtual Care Delivery Apps will allow us to create a marketplace where virtual care takes place, centered around objective clinical diagnostic information. We believe that the Cue Integrated Care Platform will help improve access to care while driving down healthcare costs and improving outcomes. In turn, we anticipate payors will begin to reimburse for our tests and other products offered under our Cue Integrated Care Platform. We believe that all of these dynamics will help create what we call the Cue Virtual Care Marketplace.



* Depicts future product developments.

Our Key Differentiators

We believe the following attributes differentiate us from other diagnostic solutions and digital health companies:

- ***Consumer-centric.*** The Cue Integrated Care Platform is intended to revolutionize the way individuals and healthcare providers access diagnostic testing at home, at work, or at the point-of-care. Our Cue Integrated Care Platform is designed to deliver a superior user experience in any setting, one that is fully-guided, fast, accurate, and easy to use and that puts the consumer in control of their health data.
- ***Lab-quality diagnostics anywhere in minutes.*** Combining the sophistication and accuracy of complex molecular testing systems with the simplicity, convenience and speed of a consumer electronic device, our Cue Health Monitoring System has been developed to deliver highly specific and sensitive results within minutes.
- ***Extensible platform approach.*** We designed our technology, platform and infrastructure to be versatile in accommodating a wide range of tests by addressing both main analytical modalities used in diagnostic testing, immunoassays and NAAT. We believe our flexible platform will permit our planned future menu of tests to cover a large portion of diagnostic solutions typically offered by a traditional lab.
- ***Vertically-integrated, automated and scalable production infrastructure.*** Our proprietary technology was designed to allow us to optimize our system across the full product life cycle from design to manufacturing. Our integrated cartridge manufacturing and bio-production, including enzymes and chemistry, ensure the quality of our finished product.
- ***Scaled and growing installed base.*** We have shipped over 115,000 Cue Readers across the United States as of August 31, 2021, including Cue Readers placed through our agreement with the U.S. DoD and through our other customer agreements, resulting in a broad and active installed base, diversified across industries, locations and end-markets such as schools, essential businesses, nursing homes, hospitals, physicians' offices, dental clinics, sports and other live event venues, and other settings around the country.

Our Market Opportunity

We believe that there is substantial market opportunity for a consumer-oriented care platform that sits at the nexus of healthcare and technology. We estimate that global healthcare expenditures in 2021 will reach $8.8 trillion. We estimate that the total addressable markets, or TAM, for digital health and diagnostics were approximately $120 billion and $85 billion, respectively, in 2020. Of the estimated $85 billion diagnostics market, we estimate that

at-home and point-of-care testing solutions accounted for approximately $30 billion, of which, according to our internal estimates, approximately $20 billion was attributable to point-of-care testing solutions while approximately $10 billion was attributable to at-home testing solutions. We further estimate that the TAM for point-of-care diagnostics will grow to up to $51 billion by 2025. In 2021, we estimate the COVID-19 point-of-care diagnostic market alone to be approximately $12 billion. We believe that the digital health and diagnostics markets that we are targeting are not only capable of being quickly disrupted by our Cue Integrated Care Platform, but that our TAM will continue to expand as individuals increasingly seek convenience and accessibility in their healthcare services, as awareness of our brand and platform offering grows, and as we build out our planned integrated service offering, including telehealth and e-prescription capabilities. Additionally, we believe healthcare providers and payors will continue to look for creative solutions to optimize care and cost efficiency, while employers will aim to maintain productivity and continuity.

Our Growth Strategy

Key elements of our growth strategy include:

- ***Expand our menu of tests and continue to innovate and enhance our platform.***
- ***Drive ecosystem adoption.***
- ***Continue to expand our installed base and distribution network to enable pull-through of our future extended care offerings.***
- ***Increase adoption through value-based selling and payor reimbursement.***
- ***Continue to build the Cue brand.***
- ***Scale manufacturing capabilities to capitalize on demand.***
- ***Expand our global footprint.***

Our Go-To-Market Strategy

Our go-to-market strategy is powered by an in-house direct sales team focused on target customer segments including: the public sector, healthcare providers, large enterprises, and individual consumers. Our go-to-market strategy is further complemented by our marketing team's strategy to raise Cue's overall brand awareness and value proposition.

Our marketing strategy is focused on building strong brand awareness for the Cue Integrated Care Platform as a molecular at-home diagnostic solution, with relevant, measurable value for all of our customer segments. Our marketing drives across our owned media channels (website and social networks), press releases, scientific publications, industry engagement with key stakeholders, partnerships with key opinion and market leaders, and targeted marketing through digital and non-digital channels. We anticipate investing further, using account-based marketing strategies to accelerate brand awareness and increase demand, and thus sales opportunities, across our targeted markets.

Our direct sales team engages with prospective clients and seeks to identify the best sales channel based on each client's needs. Our go-to-market strategy is focused on allowing us access to the end user, through our Cue Integrated Care Platform, even if the individual was acquired via our direct sales organization or through an outside sales channel. For example, if an individual obtained a Cue Health Monitoring System through their self-insured employer's COVID-19 return-to-work efforts or as a result of government-supported distribution, we can nonetheless directly engage with the end user through the Cue Health App and potentially convert them to using our planned future tests and other products we may develop. As a result, we expect that we will be able to fulfill market demand through our internal and external sales channels, while maintaining an important direct customer relationship for our future product enhancements and care offerings.

Additionally, our relationship with the U.S. DoD formed an important foundation of our initial go-to-market strategy. Our relationship with U.S. DoD helped establish our domestic manufacturing infrastructure as a critical component of ongoing national healthcare infrastructure. Our relationship with the U.S. DoD also helped commercialize the Cue Health Monitoring System as part of a critical, decentralized, national diagnostic infrastructure for ongoing pandemic management. In addition, the development of Cue Readers alongside our COVID-19 Test Kits has significantly accelerated our installed base growth, which we believe will enable continued

distribution of our COVID-19 Test Kit as well as pull-through of our planned future products to key federal, state and other government agencies. Through our U.S. DoD agreement, the Cue Health Monitoring System and COVID-19 Test Kits have been deployed to over 280 school districts, nursing homes, hospitals, public health facilities and organizations, essential businesses, correctional facilities and other public sector users, as of August 31, 2021.

Demand for our COVID-19 Test Kits currently exceeds our manufacturing capacity. As a result, and in light of our existing commitments under the U.S. DoD agreement and to existing customers, we are strategically selecting new customers based on the following considerations: order volume, industry diversification and potential interest in our expected future test menu.

Our direct sales team is comprised of experienced sales professionals focused on the following four categories:

- **Public Sector Sales**: Our public sector sales team identifies new opportunities within federal, state and local government agencies. While we expect that revenue from other categories of customers will become a larger component of revenue over time, our public sector sales strategy continues to look to identify opportunities with new and existing federal, state and local government agency customers.
- **Enterprise Sales**: Our enterprise sales team identifies major self-insured enterprises such as Fortune 500 companies with large covered employee populations as well as small-to-medium sized businesses with healthcare plan partners and employee benefits offerings. We believe that enterprise customers will want to utilize our integrated care solutions for their employees and their families, both on-premise and at-home.
- **Healthcare Provider Sales**: Our healthcare provider sales strategy targets major healthcare systems and healthcare professionals such as hospital systems, private clinics and concierge health systems, and physicians' offices. Relationships with these customers, such as our current relationship with the Mayo Clinic, help validate our platform, and we believe will help accelerate marketplace adoption of our products.
- **Direct-to-Consumer Sales**: Our direct-to-consumer sales team identifies opportunities through online and offline retail channels such as e-commerce and in-store sales.

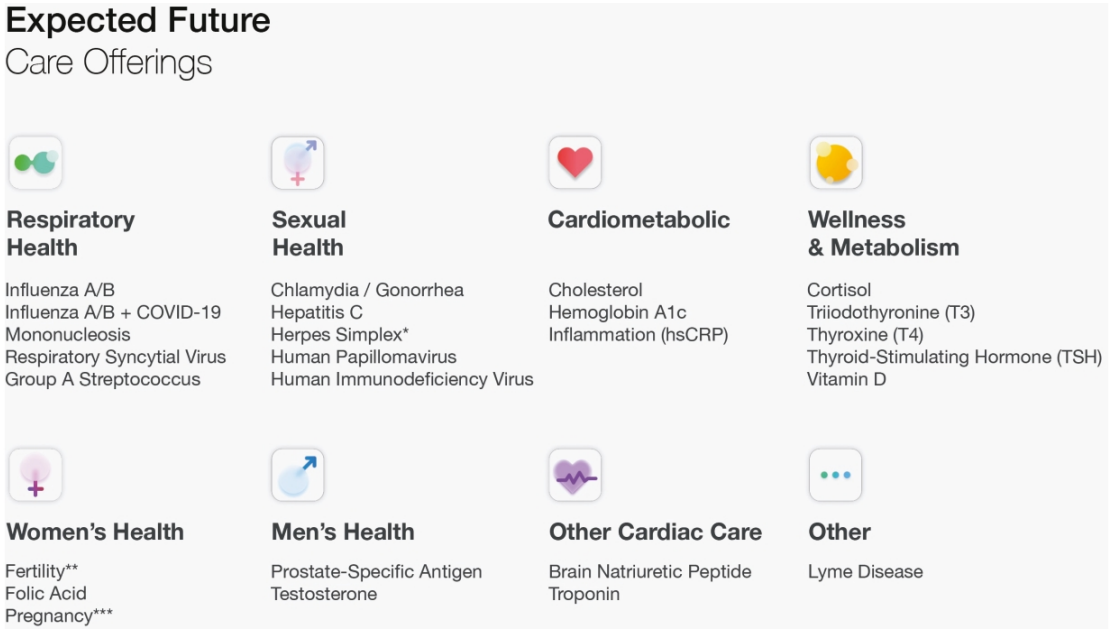
Our First Product Offering – Cue COVID-19 Test

Our COVID-19 test, consisting of our Cue Reader and COVID-19 Test Kit (Cue COVID-19 Cartridge and Cue Wand), is our first commercially available test. It is designed to detect SARS-CoV-2, the virus that causes COVID-19. Our COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use without physician supervision or a prescription. Internationally, we have also received the CE mark in the European Union, as well as Interim Order authorization from Health Canada, which is the department of the Government of Canada responsible for national health policy, for both professional point-of-care and self-testing, which is similar to over-the-counter EUA authorization in the United States. In June 2021, our COVID-19 test also received regulatory approval from the Central Drugs Standard Control Organisation, or CDSCO, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India. Our COVID-19 test provides highly accurate, lab-quality results, including for emerging variants, directly to connected mobile smart devices in about 20 minutes. A recent independent study conducted by researchers at the Mayo Clinic found that the overall concordance between our COVID-19 test and clinical laboratory tests using NAAT was 97.8%. In December 2020, our COVID-19 test was ranked by the FDA Reference Panel testing as the most sensitive among direct nasal swab point-of-care tests.

Our COVID-19 test is authorized for use by both symptomatic and asymptomatic individuals, adults and children aged two and older with adult assistance. With an easy-to-use, fully guided experience, our COVID-19 test offers convenience, privacy, and the ability to test frequently.

Our Expected Future Care Offerings

The following graphic illustrates our expected future care offerings:



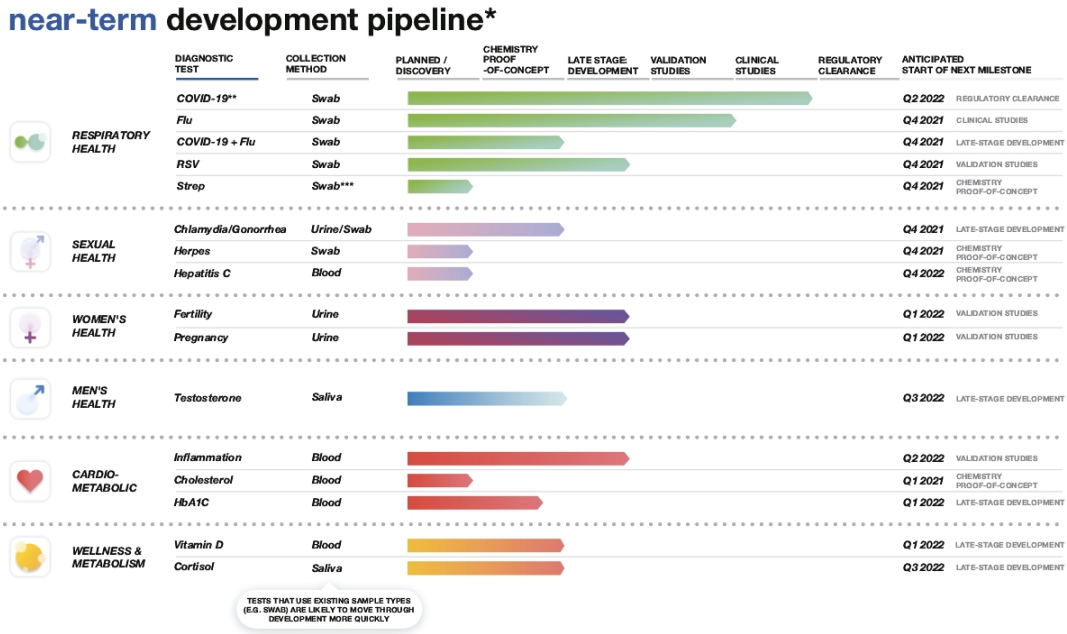
* HSV-1 & HSV-2
** Luteinizing Hormone (LH)
*** Human chorionic gonadotropin (hCG)

Our COVID-19 Test Kit is currently our only commercially available test. Our expected future care offerings include tests and other products across multiple categories, including respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. We are currently developing both the diagnostic tests and the accompanying software solutions in the virtual care delivery applications to support our planned holistic care offerings as part of our Cue Integrated Care Platform. We expect to begin submitting additional tests for FDA authorization or clearance in the second half of 2022. Further, over time, we intend to pursue future authorizations, clearances and approvals globally, including in the European Union, Australia, Brazil, Canada, India, Japan, within the Middle East, Singapore and the United Kingdom, and other countries. In public communications, FDA officials have indicated that they may be more amenable to approving tests for many diseases for home use as a result of lessons learned from the COVID-19 pandemic, especially testing solutions with telehealth capabilities.

We believe our expected future test menu expansion benefits from:

- our technical development capabilities that have led to an authorized COVID-19 test and multiple tests in late-stage technical development;
- our understanding of the regulatory pathways, including FDA authorization or clearance, for the various diagnostic tests; and
- our test-agnostic production capacity that we believe will provide us the flexibility to meet our customers' needs.

The graphic below illustrates our near-term development pipeline:



* This graphic does not reflect our full development pipeline but rather those of our tests that are furthest along in development. This graphic reflects progress towards 510(k) clearance.

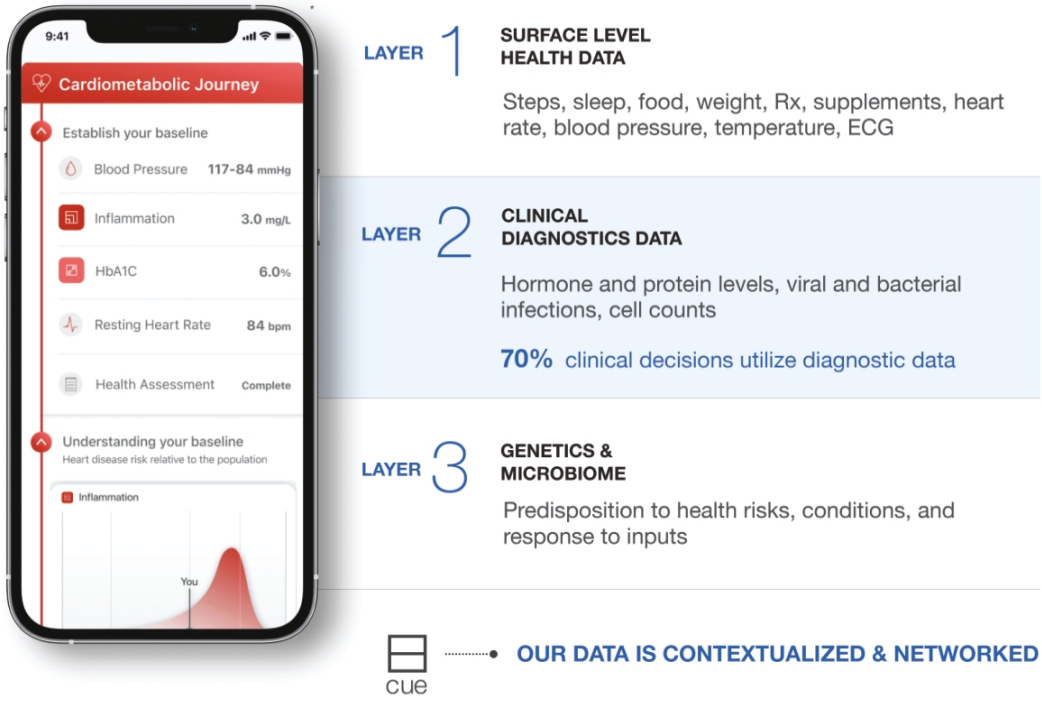
** Our COVID-19 test has been authorized by the FDA under two EUAs. This graphic reflects progress towards 510(k) clearance. Our COVID-19 test has also received regulatory approval from the CDSCO for professional point-of-care use in India, the CE mark in the European Union and Interim Order authorization from Health Canada.

*** Throat swab sample may be required.

We currently have five tests that we consider to be in late-stage technical development: flu, RSV, pregnancy, fertility, and inflammation. We consider a test to be in late-stage technical development when we have developed a working prototype Cue Cartridge in its final form factor, capable of running its intended sample type using its relevant Cue Wand. When a test is in late-stage technical development, we believe that all or the majority of the technical risk has been eliminated, and the test performance is expected to meet regulatory and marketplace requirements. At this stage, the relevant test is ready or nearly ready for verification and validation studies. In addition to completing late-stage technical development, all of our planned tests will be required to complete validation and clinical studies. With the exception of our fertility test for over-the-counter at-home use, we generally expect that our expected future tests will then need to receive regulatory authorization, clearance or approval before they can be commercialized. See the section titled “Business—Expected Future Care Offerings” for additional information regarding our current and planned tests.

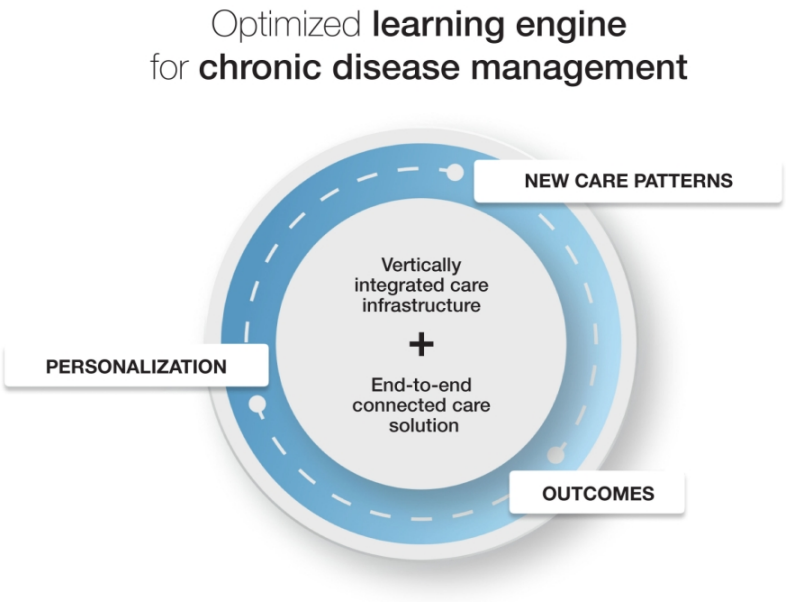
Chronic Disease Management

We believe chronic disease management will benefit from an integrated care platform that pulls in multiple layers of health information and connects them to digital health coaching and other interventions. In addition to assisting in initial diagnosis of chronic disease, diagnostic tests help measure the impact of interventions and can help optimize care patterns over time. Pulling in genetic information and other data streams can personalize and optimize care for sub-cohort patient populations. The graphic below illustrates one example of how we anticipate that the Cue Integrated Care Platform will be able to be used for chronic disease management.



* Depicts future product developments.

The Cue Integrated Care Platform has the potential to streamline how consumers with chronic conditions access the diagnostic data they need and the associated provider consultations. By making it more convenient to obtain the diagnostic information that measures the present state of a chronic condition, we believe the platform will be able to help drive adherence as people can see the impact more quickly of the various interventions such as medications and digital health coaching. In addition, we anticipate that our integrated care platform will facilitate ongoing care management by allowing people to have a more comprehensive picture of their health through the planned integration of third-party sensors and applications that will help monitor activity levels, diet, and sleep.



Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include, but are not limited to, the following:

- We have a limited operating history, which may make it difficult to evaluate our current business and predict our prospects and likelihood of success.
- We have incurred significant losses since our inception, and only recently started generating revenue from commercial sales. We may incur additional significant losses in the future, and we may never become profitable on a sustainable basis.
- If the FDA or other regulatory bodies revoke or terminate our EUAs or other regulatory authorizations for our COVID-19 test, we will be required to stop commercialization of our Cue Readers and COVID-19 Test Kits unless we can obtain 510(k) or other clearance or approval for our COVID-19 test and its currently authorized uses.
- Our near-term success is dependent on the continued commercialization of our COVID-19 test. If our COVID-19 test is unable to attain or maintain market acceptance or be successfully commercialized, our business could be materially adversely affected.
- Our long-term success will depend on the success of our COVID-19 test and a number of other factors, including widespread market adoption of our Cue Health Monitoring System, Cue Virtual Care Delivery Apps and the overall Cue Integrated Care Platform and our ability to introduce new tests for use with our Cue Health Monitoring System.
- Our revenue for at least the near term will almost exclusively depend on sales of our COVID-19 test until we can develop, obtain regulatory clearance or other appropriate authorization for, and commercialize additional tests.

- We currently rely upon the U.S. DoD and a very small number of other customers for almost all of our current product revenue. As a result, unless and until we can further diversify our customer base and sources of revenue, the loss of any of these customers, or a decline in the amount of our COVID-19 tests purchased by or sold to these customers, could materially adversely affect our business, financial condition and results of operations.
- We may encounter difficulties in managing our growth, which could adversely affect our operations.
- The diagnostic testing market is extremely competitive and rapidly evolving, making it difficult to evaluate our business and future prospects.
- If the Cue Health Monitoring System fails to achieve broad adoption by or support from the medical and professional community, key opinion leaders and other key participants in the healthcare system, our business and prospects may be materially adversely affected.
- We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.
- We have limited experience manufacturing our products in commercial quantities; if we are unable to manufacture our products in the required quantities in a timely manner, our business could be materially adversely affected.
- If we, our suppliers or our contract manufacturers experience significant disruptions to our or their manufacturing capabilities or ability to source needed supplies and materials, our business may be materially adversely affected.
- Our patent or other intellectual property protection for the Cue Health Monitoring System, products and Cue Integrated Care Platform may not be sufficient to prevent competitors from developing and commercializing tests and platforms similar to or otherwise comparable to our Cue Test Kits, products and Cue Integrated Care Platform, which could materially adversely affect our business and prospects.

Corporate Information

We were incorporated in February 2010 as Ruubix, a California corporation, and changed our name to Cue Inc. in April 2014. In December 2017, we reincorporated in the State of Delaware and changed our name to Cue Health Inc. Our principal executive offices are located at 4980 Carroll Canyon Road, Suite 100, San Diego, California, 92121, and our telephone number is (858) 412-8151. Our website address is http://www.cuehealth.com. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Trademarks and Tradenames

We own or have rights to, or have applied for, trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. Other trademarks, service marks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this prospectus are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

Channels for Disclosure of Information

Following the completion of this offering, we intend to announce material information to the public through filings with the Securities and Exchange Commission, or the SEC, our website (http://www.cuehealth.com), press releases, public conference calls, and public webcasts. We use these channels, as well as social media, to communicate with our members, clients, and the public about our company, our services and other issues. It is

possible that the information we post on social media could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels.

Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the federal securities laws. As a result, we may take advantage of reduced reporting requirements that are otherwise applicable to public companies, including delaying auditor attestation of internal control over financial reporting, providing only two years of audited financial statements and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus and reduced executive compensation disclosures. We may remain an emerging growth company until the end of 2026. However, if certain events occur prior to the end of 2026, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests. In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company.

The Offering

Common stock offered by us	12,500,000 shares.
Underwriters' option to purchase additional shares	1,875,000 shares.
Common stock to be outstanding immediately following this offering	143,766,583 shares (or 145,641,583 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $179.2 million (or approximately $207.1 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, for the continued commercial scale up of our activities and build out our corporate infrastructure, other than the scale up of manufacturing facilities and capabilities, including the hiring and training of sales and marketing personnel and to fund marketing initiatives and for the hiring and training of other personnel; the continued scale up of our manufacturing facilities and capabilities; research and development to continue to develop each of our planned tests in our near-term development pipeline; and the remainder, if any, for working capital and other general corporate purposes. We may use a portion of the net proceeds for acquisitions or strategic investments in complementary businesses, services, products or technologies. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time. See the section titled "Use of Proceeds" for more information.
Directed share program	At our request, the underwriters have reserved up to 5.0% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers and employees. Shares purchased through this program by our directors, officers and employees will be subject to the 180-day lock-up period under the lock-up agreements described under "Shares Eligible for Future Sale—Lock-up Agreements." The sales will be made at our direction by Morgan Stanley & Co. LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. See the section titled "Underwriting" for additional information.

Risk factors	See the section titled "Risk Factors" for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Global Select Market symbol	"HLTH"

The number of shares of our common stock to be outstanding immediately after this offering is based on 131,266,583 shares of our common stock outstanding as of June 30, 2021 (including the automatic conversion of all outstanding shares of our redeemable convertible preferred stock as of June 30, 2021 into an aggregate of 83,526,065 shares of common stock immediately prior to the completion of this offering and the automatic conversion of $235.5 million in aggregate principal amount of our outstanding convertible promissory notes, or Convertible Notes, into 18,611,914 shares of common stock upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share), but excludes:

- 9,944,197 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2021, with a weighted-average exercise price of $4.93 per share;
- 1,049,043 shares of common stock subject to restricted stock units, or RSUs, outstanding as of June 30, 2021;
- 75,744 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2021 to purchase shares of common stock, with an exercise price of $0.40 per share;
- 79,882 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2021 to purchase redeemable convertible preferred stock that will automatically become warrants to purchase 79,882 shares of common stock immediately prior to the completion of this offering, with a weighted-average exercise price of $1.12 per share;
- 1,138,635 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, as of June 30, 2021, of which our board of directors granted stock awards covering 128,000 shares of common stock to certain of our non-employee directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part;
- 14,173,771 additional shares of common stock that are available for future issuance under our 2021 Stock Incentive Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Stock Incentive Plan, of which our board of directors granted awards covering 9,763,966 shares of common stock to certain of our employees and executive officers and an additional 56,250 shares of common stock, based on the initial public offering price of $16.00 to certain of our non-employee directors, in each case, effective immediately prior to the commencement of trading of our common stock on the Nasdaq Stock Market; and
- 2,834,754 additional shares of common stock that are available for future issuance under our 2021 Employee Stock Purchase Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

- the automatic conversion of all outstanding shares of our redeemable convertible preferred stock outstanding as of June 30, 2021 into 83,526,065 shares of our common stock immediately prior to the completion of this offering;
- the automatic conversion of our outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock upon the closing of this offering, based on accrued interest through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share;
- the conversion of outstanding warrants to purchase 79,882 shares of our redeemable convertible preferred stock into warrants to purchase 79,882 shares of common stock, which will occur automatically immediately prior to the completion of this offering;
- no exercise of the outstanding stock options or settlement of outstanding RSUs described above;
- no exercise of the outstanding warrants described above;

- no exercise by the underwriters of their option to purchase 1,875,000 additional shares of our common stock; and
- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and our amended and restated bylaws immediately prior to the completion of this offering.

See the section titled “Capitalization” for more information.

Summary Financial Data

The following tables set forth a summary of our historical financial data as of and for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2019 and 2020 and the summary balance sheet data as of December 31, 2020 from our audited financial statements that are included elsewhere in this prospectus. The summary statement of operations data for the six months ended June 30, 2020 and 2021 and the summary balance sheet data as of June 30, 2021 have been derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any other period in the future and our interim results are not necessarily indicative of our expected results for the year ending December 31, 2021. You should read the following summary financial data together with our financial statements and the related notes included in this prospectus and in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The summary financial data included in this section are not intended to replace the audited financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by the audited financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Year Ended December 31,		Six Months Ended June 30,	
	2019	2020	2020	2021
(in thousands, except share and per share data)			(unaudited)	
Revenue:				
Product revenue	$ —	$ 15,391	$ —	$ 201,922
Grant and other revenue	6,626	7,562	4,960	—
Total revenue	6,626	22,953	4,960	201,922
Operating costs and expenses:				
Cost of product revenue[1][2]	—	14,951	—	85,177
Sales and marketing[1]	88	714	45	1,959
Research and development[1]	21,405	28,478	19,680	12,071
General and administrative[1]	5,900	23,936	3,764	23,252
Total operating costs and expenses	27,393	68,079	23,489	122,459
Income (loss) from operations	(20,767)	(45,126)	(18,529)	79,463
Interest expense	(152)	(984)	(788)	(9,964)
Change in fair value of redeemable convertible preferred stock warrants	4	(1,289)	(20)	(190)
Change in fair value of convertible notes	—	—	—	(23,254)
Other income (expense), net	309	47	59	61
Net income (loss) before income taxes	(20,606)	(47,352)	(19,278)	46,116
Income tax expense	—	—	—	(13,276)
Net income (loss)	$ (20,606)	$ (47,352)	$ (19,278)	$ 32,840
Basic net income (loss) per share attributable to common stockholders[3]	$ (1.31)	$ (2.90)	$ (1.21)	$ 0.23
Weighted-average number of shares of common stock used in basic net income (loss) per share attributable to common stockholders[3]	15,760,246	16,315,730	15,909,439	18,617,247
Diluted net income (loss) per share attributable to common stockholders[3]	$ (1.31)	$ (2.90)	$ (1.21)	$ 0.22

(in thousands, except share and per share data)	Year Ended December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Weighted-average number of shares of common stock used in diluted net income (loss) per share attributable to common stockholders[3]	15,760,246	16,315,730	15,909,439	26,036,337
Pro forma basic net income (loss) per share attributable to common stockholders (unaudited)[4]		$ (1.04)		$ 0.44
Pro forma weighted-average number of shares of common stock used in basic net income (loss) per share attributable to common stockholders (unaudited)[4]		120,478,100		128,036,801
Pro forma diluted net income (loss) per share attributable to common stockholders (unaudited)[4]		$ (1.04)		$ 0.42
Pro forma weighted-average number of shares of common stock used in diluted net income (loss) per share attributable to common stockholders (unaudited)[4]		120,478,100		135,391,595

(1) Includes stock-based compensation expense as follows:

(in thousands)	Year Ended December 31, 2019	Year Ended December 31, 2020	Six Months Ended June 30, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Cost of product revenue	$ —	$ —	$—	$ 343
Sales and marketing	—	1	—	26
Research and development	45	98	13	1,444
General and administrative	291	3,064	84	3,778
Total stock-based compensation expense	$336	$3,163	$97	$5,591

During the six months ended June 30, 2021, $0.1 million of stock-based compensation expense was capitalized to inventory during the manufacturing process.

(2) Includes $2.1 million and $10.5 million of depreciation and amortization expense for the year ended December 31, 2020, and for the six months ended June 30, 2021, respectively.

(3) See Note 14 to our audited financial statements and to our unaudited interim condensed financial statements, each included elsewhere in this prospectus, for details on the calculation of basic and diluted net income (loss) per share attributable to common stockholders, and the weighted-average number of shares used in the computation of the per share amounts.

(4) The unaudited pro forma basic and diluted net income (loss) per share attributable to common stockholders has been computed to give effect to the following items as if the transaction occurred at beginning of the earliest comparative period presented, January 1, 2020 (i) the conversion of all outstanding shares of redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock upon completion of this offering, (ii) the conversion of all outstanding Convertible Notes into an aggregate of 18,611,914 shares of our common stock upon completion of this offering and the elimination of the related $23.3 million change in fair value of Convertible Notes and $1.0 million of interest expense related to Convertible Notes for the six months ended June 30, 2021, (iii) $63.5 million from the acceleration of debt discount and non-cash expense from Convertible Notes recognized for the year ended December 31, 2020, (iv) $1.3 million and $0.2 million elimination of the change in fair value of redeemable convertible preferred stock for the year ended December 31, 2020 and six months ended June 30, 2021, respectively, (v) $14.9 million of stock-based compensation expense related to the forgiveness of promissory notes from certain executives, accelerated vesting of RSUs of an executive, and grants of common stock to directors in connection with this initial public offering for the year ended December 31, 2020. Our effective tax rate for the year ended December 31, 2020 was 0%, therefore, a tax effect is not given to the pro forma adjustments.

The following table sets forth the computation of the Company's unaudited pro forma basic and diluted net income (loss) per share (in thousands, except share data):

	Year Ended December 31, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Numerator:		
Net income (loss)	$ (47,352)	$ 32,840
Elimination of change in fair value of convertible notes	—	23,254
Eliminations of interest expense related to convertible notes	—	1,026
Discount and non-cash expense on convertible notes	(64,038)	—
Elimination of change in fair value of redeemable convertible preferred stock warrants	1,289	190
Stock-based compensation expense in connection with IPO[1]	(14,867)	—
Pro forma net income (loss) attributable to common stockholders	$ (124,968)	$ 57,310
Minus: Income allocated to participating securities	—	991
Pro forma net income (loss) attributable to common stockholders - basic	$ (124,968)	$ 56,319
Plus: Income allocated to non-participating securities	—	53
Pro forma net income (loss) attributable to common stockholders - diluted	—	56,372
Denominator:		
Weighted-average common shares outstanding – basic	16,315,730	18,617,247
Pro forma adjustments to reflect:		
Redeemable convertible preferred stock	83,526,065	83,526,065
Conversion of convertible notes	18,611,914	18,611,914
Weighted-average shares subject to nonrecourse notes	1,759,017	7,016,201
Accelerated vesting of RSUs	137,374	137,374
Issuance of common stock to directors	128,000	128,000
Pro forma weighted average common shares outstanding – basic	120,478,100	128,036,801
Dilutive potential common stock issuable:		
Non-participating common shares	—	7,354,794
Pro forma weighted-average shares outstanding – diluted	120,478,100	135,391,595
Pro forma net income (loss) attributable to common stockholders per share		
Basic	$ (1.04)	$ 0.44
Diluted	$ (1.04)	$ 0.42

(1) Expense related to the forgiveness of promissory notes of Mr. Khattak and Mr. Sever and the vesting of RSUs and option grants to certain executives and directors in connection with this offering.

Outstanding anti-dilutive securities not included in the unaudited pro forma diluted net income (loss) per share attributable to common stockholders were as follows (in common stock equivalent shares):

	Year Ended December 31, 2020 (unaudited)	Six Months Ended June 30, 2021 (unaudited)
Stock options	8,633,419	1,926,752
Restricted stock units	—	911,669
Unvested common stock subject to restricted stock purchase agreements	3,535,073	—
Common stock warrants	155,626	—
Total	12,324,118	2,838,421

(in thousands)	As of June 30, 2021		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$246,326	$ 246,326	$ 425,526
Working capital[3]	233,965	233,965	413,165
Restricted cash, non-current	6,000	6,000	6,000
Total assets	631,312	631,312	810,512
Redeemable convertible preferred stock warrant liabilities	1,521	—	—
Convertible notes	258,734	—	—
Finance lease liabilities, net of current portion	1,694	1,694	1,694
Total liabilities	516,321	255,022	255,022
Redeemable convertible preferred stock	176,323	—	—
Additional paid-in capital	16,264	506,784	685,984
Accumulated deficit	(77,596)	(130,494)	(130,494)
Total stockholders' (deficit) equity	(61,332)	376,290	555,490

(1) The pro forma balance sheet data gives effect to (i) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately prior to the completion of this offering, (ii) the automatic conversion of all of our outstanding $235.5 million aggregate principal amount convertible promissory notes, or Convertible Notes, into 18,611,914 shares of common stock upon the completion of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, (iii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock immediately prior to the completion of this offering, and (iv) the automatic conversion of all of our outstanding warrants to purchase redeemable convertible preferred stock into warrants to purchase common stock, and the related reclassification of our redeemable convertible preferred stock warrant liabilities to additional paid-in capital immediately prior to the completion of this offering.

(2) The pro forma as adjusted balance sheet data reflect: (i) the pro forma adjustments set forth above, and (ii) the issuance and sale of 12,500,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities, including current finance lease liabilities of $1.3 million. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this prospectus, including our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation, or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Strategy

We have a limited operating history, which may make it difficult to evaluate our current business and predict our prospects and likelihood of success.

We have a limited operating history. We were incorporated in 2010, but prior to commercialization of our COVID-19 Test Kit for use with our Cue Health Monitoring System in the third quarter of 2020, our activities were largely focused on our research and development efforts and we only started realizing revenue from commercial product sales in August 2020. Our COVID-19 test is currently our only commercially available test. Our limited commercial operating history may make it difficult to evaluate our current business and predict our future performance. Any assessment of our future revenue potential, profitability or prospects for our future success is subject to significant uncertainty. We have encountered and will continue to encounter significant risks and difficulties frequently experienced by early commercial-stage companies in rapidly evolving industries. If we do not address these risks successfully, it could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We have incurred significant losses since our inception, and only recently started generating revenue from commercial sales. We may incur additional significant losses in the future, and we may never become profitable on a sustainable basis.

We have incurred significant losses since our inception in 2010, including net losses of $20.6 million and $47.4 million for the years ended December 31, 2019 and 2020, respectively. For the six months ended June 30, 2021, we had a net income of $32.8 million. As of June 30, 2021, we had an accumulated deficit of $77.6 million. While we were profitable for the first time in the first half of 2021, we cannot assure you that we will be able to continue to be profitable on an ongoing basis, either in the near term or longer term. In connection with the completion of this offering, we expect to incur an incremental non-cash charge of $39.0 million as a result of the automatic conversion of our Convertible Notes issued in May 2021. We estimated approximately $62.3 million of discount on these notes that will be partially offset by the $23.3 million of noncash expense relating to the change in the fair value of the Convertible Notes that was recognized in our statements of operations for the six months ended June 30, 2021. If the offering closes after September 30, 2021, we expect the total discount to be incurred in connection with the automatic conversion of the Convertible Notes upon completion of this offering would increase to $78.5 million plus accrued interest at the time of closing. We also expect to recognize approximately $14.9 million of non-cash stock-based compensation expense related to the forgiveness of certain promissory notes from our executives and the vesting of RSUs and option grants to executives and directors in connection with this offering. We expect to recognize this non-cash stock-based compensation expense in the period in which this offering is completed. Of the non-cash items described above, charges related to Convertible Notes will not be tax deductible. As a result of these noncash charges, we may have a net loss for the quarter in which this offering is completed and for the fiscal year ending December 31, 2021. We may continue to incur losses both in the near term and longer term as we continue to invest significant additional funds to scale up our business, including continuing to build out our commercial organization and corporate infrastructure, continuing to build out our manufacturing capabilities and engaging in continued research and development as we work to expand our menu of available tests and also as we incur additional costs associated with operating as a public company. Prior to August 2020, we had never generated any revenue from the commercial sale of products, and we had devoted substantially all of our resources to the research and development of our Cue Health Monitoring System. We only first started realizing revenue from commercial product sales in August 2020 following receipt of our first Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, in June 2020 for our COVID-19 test. Our COVID-19 test includes a Cue Reader and a COVID-19 Test Kit comprised of a Cue COVID-19 Cartridge and a Cue Wand. Since receiving our first FDA EUA, we have incurred significant additional expenses in connection with the commercial scale up of our business, including costs associated

with scaling up our manufacturing operations, costs associated with the production of our COVID-19 test, sales and marketing expenses, and costs associated with the hiring of new employees, the growth of our business and building out our corporate infrastructure. In addition, we will incur significant additional expenses as we become a public company, further grow our business and continue to roll out our COVID-19 tests to the marketplace, pursue new customers and look to develop and commercialize new tests and other products for use with our Cue Integrated Care Platform. Therefore, our losses may continue to increase for at least the near term, if not longer. We are unable to predict whether or when we will become profitable on a sustained basis. Our ability to sustain profitability is based on numerous factors, many of which are beyond our control, including, among other factors, market acceptance of our products, the length of the COVID-19 pandemic, future product development, our market penetration and margins and our ability to expand our menu of tests. We may not be able to sustain or increase profitability in the future. Our inability to achieve and maintain profitability, whether in the near term or longer term, may make it difficult to continue to grow our business and accomplish our strategic objectives, and could materially adversely affect our business, financial condition, results of operations and future prospects.

If the FDA or other regulatory bodies revoke or terminate our EUAs or other regulatory authorizations for our COVID-19 test, we will be required to stop commercialization of our Cue Readers and COVID-19 Test Kits unless we can obtain 510(k) or other clearance or approval for our COVID-19 test and its currently authorized uses.

Our COVID-19 test is currently marketed in the United States pursuant to two EUAs we received from the FDA in June 2020, for point-of-care use, and in March 2021, for at-home and over-the-counter use without a prescription. We cannot predict how long either of these EUAs will remain in effect, and we may not receive advance notice from the FDA regarding revocation of either or both of our EUAs. If our EUAs are terminated or revoked, we will be required to cease commercialization of our COVID-19 Test Kit, unless and until we have obtained marketing authorization from the FDA through another regulatory pathway. In addition, changing policies and regulatory requirements could require us to obtain a 510(k) or other marketing authorization from the FDA for our COVID-19 test, which could limit, delay or prevent further commercialization of our COVID-19 Test Kit and could materially adversely impact our business, financial condition, results of operations and future prospects.

We also received Interim Order authorization from Health Canada for professional use in April 2021. We have begun commercialization activity in Canada, distributing to professional users. In August 2021, we received an amendment to the Interim Order authorization from Canada Health to include self-testing, which is similar to our EUA over-the-counter authorization in the United States. If the Interim Order authorization is revoked or terminated, we would lose our ability to expand into the Canadian market and would need to obtain additional authorization or approvals before we are permitted to sell any of our current or future products.

Our near-term success is dependent on the continued commercialization of our COVID-19 Test Kit. If our COVID-19 Test Kit is unable to attain or maintain market acceptance or be successfully commercialized, our business could be materially adversely affected.

Our near-term success is dependent on the continued commercialization of our COVID-19 Test Kit, which currently is our only commercially available test. The continued commercial success of our COVID-19 Test Kit will depend on many factors, some of which are outside of our control, including the following:

- our ability to continue to scale up our manufacturing and commercial capabilities so we can timely manufacture our Cue Readers, Cue Cartridges and Cue Wands in sufficient capacity to meet customer requirements and market demand;
- acceptance by key opinion leaders, healthcare systems and providers, governments and regulatory authorities, enterprise and health plan customers, consumers and others of the convenience, accuracy and other benefits offered by our COVID-19 test and our Cue Integrated Care Platform;
- the ability of our COVID-19 test to accurately detect different strains of SARS-CoV-2, the virus that causes COVID-19, created by genetic mutation or otherwise, such as the five SARS-CoV-2 variants of concern known as the Alpha, Beta, Gamma and Delta variants or other new variants that have emerged or may emerge;
- the ability of consumers and other customers to pay for or otherwise obtain payment coverage or reimbursement from third-party payors for our Cue Readers and/or our COVID-19 Test Kits;
- the length of the COVID-19 pandemic and the extent to which widespread vaccinations in the U.S. reduces demand for our COVID-19 test;

- our ability to maintain our EUAs received from the FDA or otherwise obtain requisite future regulatory approval, as well as our ability to obtain and maintain regulatory authorizations, clearances and approvals in other jurisdictions; and
- our ability to comply with all regulatory requirements applicable to our COVID-19 test, including applicable FDA marketing, manufacturing and post-market surveillance requirements and other requirements of our EUAs.

If our COVID-19 test does not gain broad market acceptance in the marketplace, it could have a material adverse effect on the broader commercial success of the Cue Health Monitoring System and our future tests.

In addition, the COVID-19 diagnostic testing market is characterized by rapid technological developments. If our COVID-19 test is rendered uncompetitive or obsolete, even if it were to gain widespread market acceptance initially, the demand for our COVID-19 test could be greatly reduced. Further, market adoption of our COVID-19 test may also be materially affected by the availability and efficaciousness of vaccines or the emergence of therapeutic treatments for COVID-19. As current or newly developed vaccines become widely administered and as current or newly developed therapeutic treatments are approved and become widely used, then market interest and the commercial opportunity for our COVID-19 test may significantly lessen or potentially even disappear.

Our long-term success will depend on the success of our COVID-19 test and a number of other factors, including widespread market adoption of our Cue Health Monitoring System, Cue Virtual Care Delivery Apps and the overall Cue Integrated Care Platform and our ability to introduce new tests for use with our Cue Health Monitoring System.

Our long-term commercial success will depend on a number of factors, some of which are beyond our control, including:

- the success of our COVID-19 test;
- the successful completion of validation and clinical studies for our anticipated future tests;
- the timely receipt of marketing authorizations, clearances and approvals from the FDA and other similar regulatory authorities for our anticipated future tests and, if required, additional marketing authorizations, clearances and approvals for our COVID-19 test;
- perceptions by the public and members of the medical community, including healthcare stakeholders, as to the convenience, accuracy and the sufficiency of clinical evidence supporting the performance of the Cue Integrated Care Platform;
- demand from the public and members of the medical community for the Cue Health Monitoring System and adoption of our anticipated menu of tests;
- the availability, perceived advantages, relative cost, relative convenience and relative accuracy of the Cue Health Monitoring System compared to products produced by our competitors;
- positive or negative media coverage of the Cue Health Monitoring System or competing products, as to its convenience, accuracy and the sufficiency of clinical evidence supporting its performance;
- the effectiveness of our marketing and sales efforts;
- unanticipated delays in manufacturing our COVID-19 Test Kits;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the continued growth of our business and the development and commercialization of additional tests;
- unanticipated delays in manufacturing, developing or launching additional tests for our Cue Health Monitoring System;
- our ability to comply with all regulatory requirements applicable to our Cue Health Monitoring Systems and our current and anticipated future tests;
- our ability to price our Test Kits, including our COVID-19 Test Kit, at an acceptable price;
- our ability to obtain, maintain enforce, protect and defend our intellectual property rights;
- our ability to produce a continued supply of Cue Readers and Cue Test Kits;

- our ability to meet the demands and the requirements of our agreements with our largest customers, including the U.S. DoD;
- limitation on use or warnings required by the FDA in our product labeling; and
- availability of, or changes in, coverage or reimbursement rates for any of our current or future tests from government or other enterprise or healthcare payors.

Our future success also depends upon customers and end users of our products having a positive experience with the Cue Integrated Care Platform in order to increase demand for our COVID-19 test as well as drive interest in our future tests. If our COVID-19 test does not meet the expectations of customers and end users, it could discourage them from purchasing additional COVID-19 tests from us or from referring our COVID-19 test to others or utilizing our future tests. Further, dissatisfied customers and end users may express negative opinions through social media or word of mouth. Any failure to meet customer and end user expectations and any resulting negative publicity could harm our reputation and future sales.

Our revenue for at least the near term will almost exclusively depend on sales of our COVID-19 test until we can develop, obtain regulatory clearance or other appropriate authorization for, and commercialize additional tests.

We expect that sales of our COVID-19 test will account for almost all or the substantial majority of our revenue until at least such time as we can commercialize additional tests or other products. As a result, our ability to execute our growth strategy and become profitable in the near term will depend upon consumer adoption of the Cue Health Monitoring System and positive experiences with our COVID-19 test. We currently have a relatively small number of customers, and our ability to acquire new customers is largely constrained by the terms of our U.S. DoD agreement through the completion of our performance of that agreement, subject to exceptions. We may not be able to successfully acquire new customers in a timely manner or at all. If we are unable to expand our customer base, we may not be able to increase our revenue. Adoption and use of our COVID-19 test will depend on several factors, including, but not limited to the accuracy, affordability and ease of use of our Cue Health Monitoring System as compared to other products, and coverage and reimbursement policies with respect to our Cue Health Monitoring System, our COVID-19 Test Kit, and products that compete with our COVID-19 test.

Because we expect virtually all of our revenue for at least the near term to be generated from sales of our COVID-19 test, the failure of our COVID-19 test to gain market acceptance or retain regulatory authorization under our EUAs may have a material adverse effect on our business, operating results and financial condition.

In addition, we are currently committing substantial financial resources, manufacturing capacity and personnel to the commercialization and manufacturing of our COVID-19 test. Allocating our available resources in such manner may negatively impact our research and development efforts for our other planned future tests, and result in a delay in our ability to bring new tests to market.

We currently rely upon the U.S. DoD and a very small number of other customers for almost all of our current product revenue. As a result, unless and until we can further diversify our customer base and sources of revenue, the loss of any of these customers, or a decline in the amount of our COVID-19 tests purchased by or sold to these customers, could materially adversely affect our business, financial condition and results of operations.

For the year ended December 31, 2020 and the six months ended June 30, 2021, the U.S. DoD accounted for approximately 58% and 83% of our product revenue, respectively, and the U.S. DoD is expected to continue to be a significant source of our revenue during the term of the U.S. DoD agreement. In addition, for the year ended December 30, 2020, sales of our Cue Readers and our COVID-19 Test Kits through Henry Schein accounted for approximately 22%. A single non-government enterprise customer accounted for approximately 14% of our product revenue during the six months ended June 30, 2021. We anticipate our initial U.S. DoD agreement will be completed by December 31, 2021, which is when we expect to receive our final payment from the U.S. DoD under the agreement. As a result, we anticipate that our revenue may decline significantly upon conclusion of this agreement (at least in the short term, if not longer), and that we will be largely dependent on new and other existing customers for our revenue at such time. See “Business—Certain Key Factors Affecting Our Performance—U.S. Department of Defense Agreement” for additional information about the potential renewal of the U.S. DoD agreement via a federal acquisition regulation-based contract, or FAR-based contract. Once the U.S. DoD agreement has been completed, and if we do not enter into a new FAR-based contract, we will be unrestricted in terms of who we can sell our Cue Test Kits to. Should we enter into a FAR-based contract upon termination of the U.S. DoD agreement, the U.S. DoD will

have the right to purchase up to 45% of our quarterly production for the duration of the contract at a specified discount to the lowest price offered by us to a commercial customer for the same products, equivalent quantities and comparable terms of sale, subject to a price floor. Any such additional contract with the U.S. DoD could constrain our ability to grow our business with non-U.S. government customers. 29 other customers were responsible for the remainder of our product revenue during the six months ended June 30, 2021, excluding certain customers who purchased our COVID-19 Test Kits and Cue Readers through our relationship with Henry Schein, and we expect an equal or greater number of customers to be responsible for the remainder of our 2021 product revenue. We will need to significantly expand our customer base in order for our business to succeed. Unless and until we can further expand and diversify our customer base and sources of revenue, the loss of the U.S. DoD or any of our other major customers, or a significant reduction in the amount of our products purchased by the U.S. DoD or any of our other major customers, would have a material adverse effect on our business, financial condition and results of operations and could have a material adverse effect on our future prospects. Our ability to acquire new customers is largely constrained by the terms of our U.S. DoD agreement through the completion of our performance of that agreement, subject to exceptions.

If the U.S. DoD terminates or fails to renew our agreement, whether due to our inability to meet our obligations under the agreement or for any other reason, including without cause, our business, results of operations, financial condition and future prospects may be materially adversely affected.

Our agreement with the U.S. DoD may be terminated by the U.S. government for convenience, without cause, or if we materially fail to comply with the provisions of the agreement, including the production requirements under the agreement. We cannot assure you that the agreement will not be terminated by the U.S. DoD prior to its completion.

In order to meet our contractual obligations under the U.S. DoD agreement, we must deliver 30,000 Cue Readers, 6,000,000 Cue COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs, which includes six quality control swabs (three positive and three negative) in each pack, to the U.S. government pursuant to an agreed upon delivery schedule, as well as achieve a sustained average of daily manufacturing capacity of approximately 100,000 Cue COVID-19 Test Kits per day over seven consecutive days by December 31, 2021. Under our agreement with the U.S. DoD, we are required to deliver to the U.S. government all of our manufacturing output of Cue COVID-19 Cartridges, subject to certain exceptions for existing contracts and for future contracts we are able to obtain waivers from the U.S. DoD. In April 2021, we received a waiver from the U.S. DoD, or the U.S. DoD Waiver, effective May 1, 2021, allowing us to distribute commercially up to 50% of our COVID-19 Test Kit production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. The U.S. DoD Waiver is currently expected to remain in effect for the duration of the U.S. DoD agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements.

The date originally specified in the agreement to meet our delivery requirements was April 11, 2021. However, we were unable to meet these requirements in the given timeframe, and therefore, in March 2021, the U.S. DoD agreed to extend this date to October 12, 2021 and in September 2021, the U.S. DoD agreed to further extend this date to December 31, 2021. As of December 31, 2020, our daily manufacturing capacity for Cue COVID-19 Test Kits was approximately 2,000 cartridges per day. As of March 31, 2021, our daily manufacturing capacity for Cue COVID-19 Test Kits increased to approximately 20,000 per day. As of August 31, 2021, our daily manufacturing capacity for Cue COVID-19 Test Kits was on average over 43,000 cartridges per day over a seven-day period with a single day peak of nearly 60,000 COVID-19 Test Kits. While we have been rapidly expanding our manufacturing capacity since the fall of 2020 and are continuing to do so by adding additional production pods, we will need to create significant additional manufacturing capacity to meet our production target of approximately 100,000 Cue COVID-19 Cartridges per day for a seven-day period by December 31, 2021. We complied with our obligation to deliver all of the Cue Readers as required under the U.S. DoD agreement. While we currently believe we will also be able to comply with the obligation to deliver 6,000,000 Cue COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs by December 31, 2021, it is possible that we will be unable to do so due to any number of internal or external factors such as delays in production, delays in the construction of any of our new production pods or issues in obtaining key components from any of our third-party suppliers needed to produce our Cue COVID-19 Test Kits. If we are unable to fulfill any of the requirements of our agreement, the agreement may be terminated or not renewed by the U.S. DoD. However, in the event the U.S. DoD was to terminate our agreement based on our inability to fulfill the delivery or production requirements under the agreement, we believe such termination is unlikely to be considered a termination for cause. Even if we are able to fulfill the requirements of the agreement, it may still be

terminated or not renewed by the U.S. DoD. If the agreement is terminated or not renewed after we satisfy our delivery obligations under the agreement, our business, results of operations, financial condition and future prospects may be materially adversely affected. In addition, if the U.S. DoD agreement is terminated by the U.S. DoD for cause, the U.S. Government may be entitled to certain remedies, including penalty payments and the grant of a non-exclusive, paid up, perpetual license from us and certain intellectual property rights for the purpose of developing the products with other contractors, potentially competitors. In addition, the U.S. government could have the right to be the exclusive purchaser of our production capacity until we meet this obligation. Upon conclusion of the U.S. DoD agreement, we anticipate that our revenue may decline significantly (at least in the short term, if not longer), and that we will be largely dependent on new and other existing customers for our revenue at such time.

Our obligations to the U.S. DoD may limit our ability to sell our COVID-19 test to other customers in the near term, including to healthcare systems and healthcare providers, enterprise customers, consumers and strategic partners.

Under our agreement with the U.S. DoD, the U.S. government is entitled to all of our manufacturing output during the term of the agreement, subject to certain exceptions for existing agreements and our ability to obtain waivers from the U.S. DoD. In April 2021, we received the U.S. DoD Waiver, which, effective May 1, 2021, allows us to distribute commercially up to 50% of our COVID-19 Test Kit production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. We anticipate that the U.S. DoD Waiver will remain in effect for the duration of the U.S. DoD agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements. Because of our obligations to the U.S. DoD under the U.S. DoD agreement, we have been and may continue to be delayed in our ability to widely roll out our COVID-19 test to other customers, including healthcare systems and healthcare providers, enterprise customers, and consumers, especially if we aren’t able to obtain additional waivers from the U.S. DoD for future customer agreements. Any delay by us in making Cue Readers and our COVID-19 Test Kits available to these other customer groups could cause us to lose any advantage we may have otherwise had as a result of our being the first company to receive an EUA from the FDA for at-home and over-the-counter use without a prescription and may allow other companies to gain market share at our expense.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

From January 1, 2020 to August 31, 2021, the number of our employees increased from 99 to 1,254 as we have been rapidly scaling up our manufacturing and corporate infrastructure during this time. We anticipate continued growth in our business operations. Our recent rapid growth has, and our continued growth is expected to, place significant strain across our organizational, administrative, and operational infrastructure. Our ability to manage our growth properly will require us to implement additional operational, financial, and managerial controls, as well as our reporting systems and procedures, and to continuously improve these controls, systems and procedures.

Our growth requires us to continue to expand our manufacturing capacity, our corporate infrastructure, hire significant additional personnel in a wide range of areas, implement new technology systems and automate equipment processes. In addition, we will need to continue to implement customer service, billing, and general process improvements and expand our internal quality assurance program. Among other areas, customer service could prove to be particularly important to us given that the Cue Health Monitoring System has only very recently been introduced to the commercial market and the lack of experience some of our potential customers will have with our products and its benefits. While we are currently undertaking improvements to our facilities, including development of additional production pods, as part of our rapid growth, such improvements may be delayed for reasons that are outside of our control. As a result of the foregoing, we cannot assure you that we will be successful in implementing any necessary increases in scale, expansion of personnel, equipment, facilities, systems or process enhancements.

In addition, needed components and supplies may not be available when required on terms that are acceptable to us, or at all, and our suppliers, as well as our contract manufacturers of Cue Readers and Cue Wands may not be able to allocate sufficient capacity in order to meet our requirements, which could adversely affect our business, financial condition and results of operations.

Given our very short history of operating a business at commercial scale and our very recent rapid growth, we cannot assure you that we will be able to successfully manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. Failure to manage our growth could, among other things, result

in increased costs, product quality and customer service issues, and hinder our ability to respond to competitive challenges. A failure in any one of these or other areas could make it difficult for us to meet market expectations for our products and could damage our reputation, which in turn could have a material adverse effect on our business, financial condition, results of operations and future prospects.

Our business model is predicated on the idea that the healthcare industry is ripe for innovative disruption and the emergence of a new healthcare paradigm. The healthcare system, particularly in the United States, has historically been very slow to change, and we cannot assure you that we will be successful in our efforts to bring about disruptive change.

The healthcare system, particularly in the United States, has historically been very slow to change. We cannot assure you that we will be successful in our goal to bring about innovative disruption and the emergence of a new healthcare paradigm. There are many different constituencies that make up the healthcare system, many of whom may have a significant interest in trying to maintain the status quo. We cannot assure you that we will not face resistance from certain participants in the healthcare system as we seek to bring about change. To the extent we encounter any such challenges, the market potential for the Cue Integrated Care Platform and our products and other current and future offerings may be more limited than we anticipate. Our success and future growth largely depend on our ability to increase awareness of the Cue Integrated Care Platform and our products and other offerings with consumers, healthcare providers, enterprises, payors and other stakeholders in the healthcare system, and on the willingness of these stakeholders to utilize the Cue Health Monitoring System, including our current and future tests, the Cue Virtual Care Delivery Apps, and the overall Cue Integrated Care Platform. Diagnostic testing in the United States and elsewhere in the world continues to rely significantly on a centralized clinical testing model. We cannot assure you that we will be successful in changing historical practices in the way diagnostic testing is done, or in our efforts to bring about connectivity within the healthcare system. Consumers and other stakeholders in the healthcare system may be slow in changing their habits and may be hesitant to use the Cue Integrated Care Platform for a variety of reasons, including:

- lack of experience with our company, Cue Integrated Care Platform and products, and concerns about the newness of our technology or that we are relatively new to the industry;
- perceived health, safety or quality risks associated with the use of a new platform and the process of an individual conducting a diagnostic test at home;
- perception that diagnostic testing can only be administered by a healthcare provider;
- traditional or existing relationships between and among healthcare stakeholders that administer, process and sell diagnostic testing;
- concerns about the privacy and security of patient information and data that is available on and that can be shared with or through our Cue Integrated Care Platform;
- competition and negative selling efforts from competitors, including competing tests and platforms and other providers of healthcare technology platforms and services; and
- perception regarding the complexity of using the Cue Health Monitoring System or Cue Virtual Care Delivery Apps.

If we are unsuccessful in bringing about the disruptive change we are seeking to achieve, the opportunity for our company may be more limited than we currently anticipate.

The diagnostic testing market is extremely competitive and rapidly evolving, making it difficult to evaluate our business and future prospects.

The market for diagnostic testing is extremely competitive. Further, the diagnostic testing industry, as well as the manner in which healthcare services are delivered more broadly, is currently experiencing rapid change, technological and scientific breakthroughs, new product introductions and enhancements and evolving industry standards, as well as the emergence of telehealth and other changes in the way healthcare services are delivered. All of these factors could affect the degree to which our products gain market acceptance or approval or result in our products being less marketable or becoming obsolete. Our future success will depend on our ability to successfully compete with established and new market participants and to keep pace with scientific and technological changes and the evolving needs of customers and the healthcare marketplace.

We will be required to continuously enhance the Cue Health Monitoring System and develop new tests to keep pace with evolving standards of care. If we do not update our products to keep pace with technological and scientific advances, our products could become obsolete and sales of our products could decline or fail to grow as expected.

Central labs continue to represent the most significant portion of the diagnostic testing market, and as a result we will be competing against very large and well-established lab companies such as Quest Diagnostics, Inc. and Laboratory Corporation of America. These companies have also expanded beyond centralized laboratory testing into home sample collection. In addition, we also face intense competition from other companies that develop or already have molecular tests, whether at point-of-care or at-home, as well as companies that have or are developing antigen and antibody tests. Competitors with diagnostic testing platforms include private and public companies, such as Abbott Laboratories, Becton, Dickinson and Company, BioMerieux SA, Bio-Rad Laboratories, Inc., Danaher Corp., Ellume Limited, Everly Health, Inc., F. Hoffman-La Roche Ltd., Fluidigm Corporation, GenMark Diagnostics Inc., Ginkgo Bioworks, Inc., Mammoth Biosciences, Inc., LetsGetChecked, Lucira Health, Inc., Mesa Biotech, Inc., Qiagen N.V., Quidel Corporation, Sherlock Biosciences, Inc., Siemens AG, Talis Biomedical Corporation, Thermo Fisher Scientific, Inc. and Visby Medical, Inc. as well as several retailers, such as The Kroger Company, Walmart Inc. and Alberstons Companies, Inc.

In addition, we may also experience competition from technology-enabled health companies such as 1Life Healthcare, Inc. (d/b/a as OneMedical), American Well Corporation, Hims and Hers Health, Inc., and Teledoc Health, Inc. We may also face competition from other companies, including other technology companies. For example, it has been publicly reported that Amazon.com, Inc. may be considering launching an at-home diagnostic testing business.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise than we do in research and development, manufacturing, obtaining regulatory clearances and approvals and regulatory compliance, and sales and distribution. Mergers and acquisitions involving diagnostic testing or other healthcare companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic products or services that are more accurate, more convenient to use or more cost-effective than our products. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or approval for our products, which could result in our competitors establishing a strong market position before we are able to enter a particular market.

Further, some of our competitors' products may be sold at prices that may be lower than our pricing, which could adversely affect our sales or force us to reduce our prices, which could harm our revenue, operating income or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability and our future growth prospects may be materially harmed.

To remain competitive, we will need to expand our test menu and continually develop improvements to our products and other offerings. We cannot assure you that we will be able to successfully compete in the marketplace or develop and commercialize new tests or improvements to our products and other offerings on a timely basis. Our competitors may develop and commercialize competing or alternative products or services and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability and could materially adversely affect our future growth prospects.

If the Cue Health Monitoring System fails to achieve broad adoption by or support from the medical and professional community, key opinion leaders and other key participants in the healthcare system, our business and prospects may be materially adversely affected.

The success of the Cue Integrated Care Platform and our business model will depend on our ability to gain wide acceptance of the Cue Health Monitoring System in the marketplace. This will require us to obtain support from members of the professional and medical community, key opinion leaders and other key participants in the healthcare system.

Our ability to obtain the support of these constituencies will depend on a number of factors, including:

- our ability to demonstrate the accuracy, ease of use, and affordability of Test Kits using the Cue Health Monitoring System;

- our ability to demonstrate the comparability of test results using the Cue Health Monitoring System to other testing methodologies, including those utilized by centralized labs, such as polymerase chain reaction, or PCR, tests, reverse transcription PCR, or RT-PCR, tests, and loop-mediated isothermal amplification, or LAMP;
- any lack or perceived lack of sufficient clinical evidence supporting the accuracy and performance of our tests;
- a willingness of constituents in the healthcare system to adopt the Cue Integrated Care Platform and our current and future tests over other diagnostic products and tests;
- overcoming any biases these constituencies may have toward the Cue Integrated Care Platform and our current and future tests relative to other diagnostic products and tests;
- the cost and reimbursement from third-party payors or other payment coverage for Cue Readers and Cue Test Kits in relation to other diagnostic products and tests;
- satisfaction with the accuracy and ease of use of the Cue Health Monitoring System and overall customer experience;
- changes in pricing and promotional efforts by competitors;
- demand for point-of-care and over-the-counter diagnostic testing;
- the effectiveness of our sales, marketing and distribution efforts; and
- adverse publicity about the Cue Health Monitoring System, including any current or future developed test kits, competitive products, or the industry as a whole, or favorable publicity about competitive products.

If our tests fail to achieve broad support from members of the professional and medical community, key opinion leaders and other key participants in the healthcare system, our business and future prospects may be materially adversely affected.

Our sales cycle with institutional customers may be lengthy and variable, which may make it difficult for us to forecast revenue and other operating results.

We expect that our sales process with healthcare systems and providers, enterprise customers, strategic partners, governments and other institutional customers will require numerous interactions with multiple individuals within any given organization and involve in-depth analysis by potential customers of our products, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of these types of customers, coupled with the fact that our product involves new technology and a new model for diagnostic testing and care paradigm, the time from initial contact with a potential enterprise or other institutional customer to our receipt of a purchase order or subscription agreement may vary significantly and may be many months or longer. Given the length and uncertainty of this expected sales cycle, we may experience fluctuations in our product revenue on a period-to-period basis.

If the Cue Health Monitoring System does not perform as expected, including with respect to accuracy, errors, defects or reliability, our reputation and market acceptance of our products could be materially harmed, and our business and reputation could suffer.

Our success depends on customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care. We believe that healthcare stakeholders are likely to be particularly sensitive to defects, errors or reliability issues in our products, including if our products fail to accurately diagnose infections with high accuracy from patient samples, and there can be no guarantee that our products will meet their expectations. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase, our menu of tests expands and our other offerings through the Cue Integrated Care Platform continue to develop.

Our products use a number of complex and sophisticated biochemical and bioinformatics processes. Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our COVID-19 test, or any diagnostic test we develop in the future, will not have performance problems. An operational, technological or other failure in one of these complex processes or

fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times or they may cause our products to malfunction. In addition, our Cue Virtual Care Delivery Apps or other technology interfaces may contain undetected bugs, errors or defects. Due to the complexity of the Cue Health Monitoring System, it may be difficult or impossible to identify the reason for any performance errors or malfunctions or reliability issues. Performance issues could increase our costs and adversely affect our business, financial condition and results of operations. In addition, failure to maintain high-quality customer support, or a market perception that we do not maintain high-quality customer support, could adversely affect our reputation and our ability to sell our Cue Health Monitoring System. We may also be subject to warranty claims or breach of contract for damages related to errors, defects or reliability issues in our products.

Further, our products are designed to be used at the customer's location by untrained individuals. We cannot provide assurance that our customers will always use our products in the manner in which we intend.

If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business may suffer, our future prospects may be materially adversely affected, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies.

Additionally, COVID-19 and many of the other pathogens for which we are developing tests are known to mutate over time. Such mutations may negatively affect the accuracy of our tests or even make our tests obsolete. The failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or test results.

Operational, technical and other difficulties adversely affecting test performance may harm our reputation, impact the commercial attractiveness of our products, increase our costs or divert our resources, including management's time and attention, from other projects and priorities. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations and adversely affect our prospects.

Our products may be subject to recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may also, under their own initiative, recall a product or service if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us or a distributor could occur as a result of an unacceptable health risk, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. A recall of any component of the Cue Health Monitoring System could be required for any number of problems. Given the number of components, determining the cause of the malfunction may be particularly challenging and costly. In addition, any recall of any component of the Cue Health Monitoring System would decrease the market for our authorized tests given the decreased availability of such instruments. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We may initiate voluntary recalls involving our commercialized products. The FDA or other agency could take enforcement action for failing to report the recalls when they were conducted. In addition, if we are required to make changes to our products to redress the deficiencies leading to the recall, we may be required to seek marketing authorization for the modified device prior to commercializing it. Any recall announcement by us or the FDA or any other governmental authority, or any changes that we make to our products as a result of such recall, could harm our reputation with customers and negatively affect our business, financial condition, and results of operations.

If we initiate a recall, including a correction or removal, for one of our commercialized products, issue a safety alert, or undertake a field action or recall to reduce a health risk, could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

The use of the Cue Health Monitoring System and Cue Virtual Care Delivery Apps requires users to follow instructions, and not adhering to such instructions may lead to negative outcomes, which could harm our business. In addition, if product users view our products as difficult to use or invasive, it could affect the degree of utilization and market adoption of our products.

The successful use of the Cue Health Monitoring System and Cue Virtual Care Delivery Apps depends on each user following the instructions provided. Any user, whether it be a healthcare stakeholder or customer at home, could experience difficulty performing a test using our Cue Health Monitoring System and Cue Virtual Care Delivery Apps if they fail to follow the instructions, or otherwise misuse the test. If healthcare stakeholders or other users utilize our tests incorrectly, or without adhering to our instructions, their test result outcomes may not be consistent with the outcomes achieved in our clinical trials. For example, if a user removes the Cue Wand from the Cue Cartridge while conducting a test on the Cue Health Monitoring System, which our instructions explicitly state not to do, they could be exposed to genetic material and the result of the user's test could return a false positive. Additionally, healthcare stakeholders and customers could find the Cue Health Monitoring System difficult to use, invasive or ultimately prefer a different diagnostic testing system. This could harm our ability to achieve the broad degree of adoption necessary for commercial success or cause negative publicity and word-of-mouth as a result of our tests not meeting user expectations and accordingly, our operating results and financial condition could be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

The Cue Health Monitoring System and the Cue Virtual Care Delivery Apps rely on access to the Internet, mobile networks and Bluetooth for connectivity.

The ability to conduct testing using the Cue Health Monitoring System and the availability of the Cue Virtual Care Delivery Apps depends on access to the Internet, mobile networks and Bluetooth connectivity and storage of data in the "cloud." Our services are designed to operate without interruption. If performance of our products is adversely affected due to lack of availability of Internet access, mobile networks or Bluetooth connectivity for any reason, or security concerns arise relating to our products reliance on these means of connectivity and data storage, our relationship with customers and users of our products and our reputation could be materially adversely affected.

The total addressable market opportunity for our current and future products may be much smaller than we estimate.

Our estimates of the total addressable market for the Cue Integrated Cate Platform are based on internal and third-party estimates as well as a number of significant assumptions. Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including market research and our own internal estimates, may prove to be incorrect. Further, the continued development of, and approval or authorizations for, vaccines and therapeutic treatments may affect these market opportunity estimates. Our market opportunity may also be limited by new diagnostic tests or other products that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for platform and products could be significantly less than we estimate. If this turns out to be the case, our potential for growth may be limited and our business and future prospects may be materially adversely affected.

If we are unable to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for our Cue Readers and Cue Test Kits, the market opportunity for our tests may be less than we expect.

Our market success is dependent upon government and commercial third-party payors providing coverage and adequate reimbursement for our Cue Readers and Cue Test Kits. While the reimbursement status for COVID-19 tests generally is still evolving, our COVID-19 tests are not currently being reimbursed by federal or state health care programs or third-party payors for at-home and over-the-counter use in the United States. However, we expect that in the future healthcare providers that purchase our COVID-19 test will look to various third-party payors, such as Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, accountable care organization, or ACOs, and other healthcare-related organizations, to cover and pay for our COVID-19 test. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Sales volumes and prices of our COVID-19 test will depend in large part on the availability of coverage and reimbursement from such third-party payors. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a clinical laboratory test is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic,

experimental, nor investigational. Even if a third-party payor covers a particular test or procedure, the resulting reimbursement payment rates may not be adequate. Coverage criteria and reimbursement rates for diagnostic tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future, which could adversely affect the market for our COVID-19 test or any test we may receive governmental or other regulatory approval for in the future. In addition, the reimbursement rate for our at-home test is uncertain. Third-party payors may require additional clinical or other data in order to cover any of our COVID-19 tests or any future test we may develop in certain settings.

Our operating results may fluctuate significantly, including without limitation, due to the prevalence of COVID-19 or other conditions addressed by our tests as well as due to seasonality, which may make our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide or may be provided by investment banking research analysts or other third parties.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for any of our authorized or approved tests, which may vary significantly;
- authorization, approval and commercialization activities relating to our Cue Test Kits, which may change from time to time;
- the timing and cost of, and level of investment in, research, development, manufacturing, regulatory and commercialization activities related to our tests, which may change from time to time;
- the size, seasonality and customer mix of the COVID-19 diagnostic testing market;
- the effect of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business;
- the effect of current and new therapeutic treatments for COVID-19 and vaccines;
- sales and marketing efforts and expenses;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective;
- changes in the productivity of our sales force;
- positive or negative coverage in the media of, or clinical publications about, the Cue Health Monitoring System or any of our current or future tests or competitive products;
- the cost of manufacturing any of the components of the Cue Health Monitoring System;
- the introduction of new tests or enhancements or technologies by us or others in the diagnostic testing industry;
- pricing pressures;
- coverage and reimbursement policies with respect to our tests and products that compete with our tests;
- expenditures that we may incur to acquire, develop or commercialize tests for additional indications, if any;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The cumulative effect of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to accurately forecast inventory needs and manufacture sufficient quantities of any component of the Cue Health Monitoring System, we may experience shortages or excesses of inventory, which could result in us having insufficient capacity to meet customer demand or lead to write-downs or write-offs of inventory.

To ensure adequate supply, we must forecast inventory needs and manufacture the components of the Cue Health Monitoring System based on our estimates of future demand. Our ability to accurately forecast demand for the Cue Health Monitoring System, including the demand for any one or more of our current or future tests, could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer and user demand for our tests or for products of our competitors, our failure to accurately forecast market acceptance of new products, unanticipated changes in general market conditions, including the production and distribution of additional efficacious vaccines or other treatments for COVID-19, seasonal demands, or regulatory matters and weakening of economic conditions or user confidence in future economic conditions. In addition, we anticipate that we will experience fluctuations in customer and user demand based on seasonality, which for COVID-19 remains unknown. However, for example, to the extent we are able to commercialize a test for influenza, we would expect our forecasts of inventory for the fall and winter seasons to reflect a significant increase in inventory for that product relative to our forecasts for the spring and summer seasons. If this expectation does not materialize, our inventory forecasts may be inaccurate, resulting in shortages or excesses of inventory. Inventory levels in excess of customer and user demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand.

In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will negatively affect our business, financial condition and results of operations. Furthermore, our inability to meet manufacturing and production requirements could cause us to lose our existing customers or lose our ability to acquire new customers which would also negatively impact our business, financial condition and results of operations.

We will seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire. As an example, our Cue COVID-19 Cartridges sold in the United States and Canada currently have a nine-month shelf life within which they must be used before they expire, and in India they currently have a four-month shelf life. Any such expiration or obsoleteness of any of our products could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

We may not be able to achieve or maintain satisfactory pricing and margins for our Cue Test Kits, which could harm our business and results of operations.

Manufacturers of diagnostic tests have a history of price competition, and we may not be able to achieve or maintain satisfactory prices for our Cue Readers or any of our current or future Cue Test Kits. The pricing of our Cue Readers or any of our Cue Test Kits could be impacted by several factors, including pressure to improve margins as a result of competitive or customer pricing pressure or a limit or decline in the amount that third-party payors reimburse our customers, which could make it difficult for customers to adopt the Cue Health Monitoring System.

Furthermore, at this time, in most cases we expect to receive payment for our over-the-counter at-home tests directly from point-of-care customers and not to bill third-party payors directly. Because our COVID-19 test is the first over-the-counter and at-home use FDA-authorized molecular diagnostic test that does not require physician supervision or a prescription, there is not a well-established market for this type of product and therefore the price that we are able to charge or the price that our customers are willing to pay may be less than what we have been able to charge to date.

If we are forced to lower the price we charge for any components of our Cue Health Monitoring System, our gross margins will decrease. In addition, if our costs increase and we are unable to offset such increase with an increase in our prices, our margins would also be adversely affected. We may be subject to significant pricing pressure, which could harm our business, financial condition and results of operations and our future prospects.

If we are not successful in developing and obtaining regulatory clearance or other authorization or approval for, and commercializing additional tests, our ability to expand our business and achieve our strategic objectives will be adversely affected.

We believe our flexible platform enables us to launch different tests for other infectious diseases in addition to COVID-19 as well as for additional clinical uses, including in the areas of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. Capitalizing on the flexibility of our Cue Integrated Care Platform is a key pillar to our strategy. We will be required to conduct significant additional research and development activities and obtain necessary regulatory clearances or other required authorizations or approvals before we are able to commercialize additional tests, and we do not expect to be able to introduce any additional tests into the commercial market before the end of 2022, at the earliest. Developing new tests requires substantial technical, financial and human resources, whether or not any tests are ultimately developed or commercialized, which may divert management's attention away from other aspects of our business. We may pursue what we believe are promising opportunities only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that certain tests or the Cue Integrated Care Platform in general has risks that were previously unknown or underappreciated. In addition, even if we successfully develop new tests, we will not be able to commercialize them unless we obtain the necessary regulatory clearance or other required authorization or approval. If we are unable to successfully develop or commercialize new tests for whatever reason, we may not be able to realize what we anticipated to be the full potential of the Cue Integrated Care Platform and our business, financial condition, results of operations and future prospects may be materially adversely affected.

If the Cue Health Monitoring System does not perform as expected, our business, operating results, reputation and future prospects may suffer.

Our success depends on our ability to provide reliable tests that enable high-quality diagnostic testing with high accuracy, ease of use, and short turnaround times. The accuracy and reproducibility we have demonstrated to date with respect to our COVID-19 test may not continue or be indicative of actual future performance as the product attains more widespread usage.

The Cue Health Monitoring System uses a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors, including human error. An operational, technological, user or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate or result in longer than expected turnaround times. Operational, technical, user and other difficulties may also adversely affect test performance. If our tests do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our business, operating results, reputation, and future prospects may suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We have been a private company since our inception and, as such, we have not had the internal control and financial reporting requirements that are required of a publicly-traded company. We are required to comply with the requirements of The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, following the date we are deemed to be an "accelerated filer" or a "large accelerated filer," each as defined in the Exchange Act, which could be as early as our first fiscal year beginning after the effective date of this offering. As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

In connection with the audits of our 2019 and 2020 annual financial statements, we identified material weaknesses in internal controls pertaining to information technology general controls, a lack of segregation of duties,

documentation and design of formalized processes and procedures, insufficient complement of qualified resources with an appropriate level of knowledge, experience and training important to our financial reporting requirements, timely reconciliation and analysis of certain key accounts and the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have concluded that these material weaknesses in our internal controls over financial reporting occurred because, prior to this offering, we were a private company and did not have the internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

Beginning in the fourth quarter of 2020, we began to take steps to address our material weaknesses through our remediation plan, which included the hiring of a Chief Financial Officer in the first quarter of 2021, and the hiring of a Chief Accounting Officer and a Vice President and Treasurer in the second quarter of 2021, documenting and formally assessing our accounting and financial reporting controls, policies and procedures, and the continued engagement of external advisors to provide financial accounting assistance in the short term. We have hired and are in the process of hiring additional personnel to improve the segregation of duties in our financial closing and reporting process and timely review of key accounts and journal entries. In addition, we have engaged external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We are evaluating the longer-term resource needs of our various financial functions. We cannot assure you that our efforts to remediate the material weakness will be successful.

If we fail to remediate the identified material weaknesses or identify new material weaknesses by the time we have to issue our first Section 404(a) assessment on the effectiveness of our internal control over financial reporting, we will not be able to conclude that our internal control over financial reporting is effective, which may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our common stock may suffer.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of Sarbanes-Oxley Act. Had we performed an evaluation and had our independent registered public accounting firm performed an audit of our internal control over financial reporting in accordance with the provisions of Sarbanes-Oxley Act, additional material weaknesses may have been identified.

We are highly dependent on our senior management team and key personnel, and we will need to hire additional personnel in connection with the current scale up and growth of our business. Our business may be materially harmed if we are unable to attract and retain personnel necessary for our growth and success.

We are highly dependent on our senior management team and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, commercial and manufacturing personnel, research and development personnel, finance and accounting personnel and other highly skilled personnel and to integrate current and additional personnel in all areas of our business. The loss of members of our senior management and other important employees could have a material adverse effect on our business. In particular, the loss of the services of our co-founders, Ayub Khattak, our President and Chief Executive Officer, and Clint Sever, our Chief Product Officer, could significantly delay or prevent the achievement of our strategic objectives and otherwise have a material adverse impact on our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a negative impact on our business, financial condition and results of operations.

Competition for skilled personnel across virtually all areas where we need to attract additional personnel is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued, and expect in the future to issue, stock options, restricted stock units or other equity awards. The value to employees of stock options, restricted stock units or other equity awards may be significantly affected by movements in our stock price, including due to events unrelated to our performance, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other employees may terminate their employment with us on short notice, even where we have employment agreements in place. We also do not maintain “key man” insurance policies on the lives of these people or the lives of any of our other employees.

Furthermore, in the last twelve months we have experienced significant growth and anticipate further significant growth as we continue to ramp up our business operations. We expect to continue to increase our headcount and to hire more specialized personnel as we grow our business. Rapid expansion in personnel could mean that less experienced people are performing important functions within our company, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, we may not be able to maintain the quality of our products or satisfy customer demand and our business may otherwise be materially harmed.

If we are unable to build-out our sales and marketing and customer support capabilities or enter into agreements with third parties for these services, we may not be successful in commercializing our COVID-19 test or our future products.

We currently have only a limited sales and marketing infrastructure, and have very limited experience in the sales, marketing, customer support or distribution of diagnostic or other commercial stage products. To achieve commercial success for our COVID-19 test or any of our future tests, we must build our sales, marketing, customer support, managerial and other capabilities or make arrangements with third parties to perform these services. We currently have limited internal sales and marketing and customer support teams in place and are in the process of hiring more employees in the near-term and plan to hire additional individuals in the future as we continue to grow our business.

Our future sales will depend in large part on our ability to develop, and substantially expand, our sales force and to increase the scope of our marketing efforts. We plan to take a measured approach to expand and optimize our sales infrastructure to grow our customer base and our business. Identifying and recruiting qualified personnel and training them in the use of the Cue Health Monitoring System, applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. In addition, our EUA authorizations with respect to our COVID-19 test specify the scope and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. It can take significant time before our sales representatives are fully trained and productive. Our business may be harmed if our efforts to expand do not generate a corresponding increase in revenue or result in a decrease in our operating margin. In particular, if we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If any future authorized test for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

In addition, the introduction of our tests into our customers' existing workflows, and in the over-the-counter and at-home contexts requires us to maintain technical, customer and user support teams. Accordingly, we need trained technical and customer and user support personnel, the market for hiring these types of personnel is very competitive. If we are unable to attract, train or retain the number of qualified technical and customer and user support personnel that our business needs, our business and prospects will suffer.

If we enter into arrangements with third parties to perform sales and marketing and customer support services, our revenue or the profitability of the revenue to us may be lower than if we were to market and sell any current or future products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future products or may be unable to do so on terms that are favorable to us. We likely would have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future products. Further, our business, results of operations, financial condition and future prospects may be materially adversely affected.

We rely on third-party vendors and consultants to assist with software and technology development and other aspects of our business. If any of these vendors or consultants do not perform as expected or if our relationship with any of them is terminated or otherwise changes, our business operations could be adversely affected.

We rely on third-party vendors and consultants to assist us with software and technology development and with other aspects of our business. We anticipate that we will continue to depend on these and other third-party relationships in order to grow our business for the foreseeable future. If our third-party vendors and consultants are unable or unwilling to provide the services necessary to support our business, or if our agreements with such vendors or consultants are terminated or we are otherwise unable to maintain these relationships, our business and operations could be adversely affected. If any of our relationships with existing third-party vendors or consultants are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all. We may also incur substantial costs, delays and disruptions to our business in transitioning such services to ourselves or other third-party vendors or consultants. In addition, third-party vendors and consultants may not be able to provide the services required in order to meet the changing needs of our business or scale as quickly as we require. Any of the foregoing could harm our business, financial condition, results of operations and competitive position.

If we are subject to orders from federal or state governments under the Defense Production Act of 1950, as amended, or the DPA, or similar federal or state legislation or other authorizations permitting the government to require companies to distribute goods, products or services or make manufacturing capacity available to or as directed by the government, our opportunity to grow our business may be adversely affected.

The DPA is a federal statute that confers upon the President of the United States a broad set of authorities to influence domestic industry in the interest of national defense. “National defense” can include emergency and disaster response and, since the start of the current COVID-19 crisis, this authority has been used on several occasions to address the public health crisis. Through the DPA, the executive branch has struck agreements with multiple companies to accelerate COVID-19 countermeasures, like N95 protective masks, testing swabs, and vaccine development, and, in September 2020, used the DPA to acquire point-of-care diagnostic testing instruments from two diagnostics industry competitors for placement in nursing homes. The government may apply the DPA, or another law or program, to our other existing contracts or a new contract to acquire our testing instruments or to direct us to distribute our products in a particular manner, and we may be likewise required to prioritize distribution to certain government agencies or other recipients, or to allocate inventory, supplies or facilities for government or government-directed use. The DPA provides that orders pursuant to the statute must “meet regularly established terms of sale or payment” and further provides that no person “shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order” under the DPA. However, compliance with the DPA could potentially cause business disruption, interfere with our commercial sales and marketing efforts, and depending on the demand, could even prevent or delay our ability to sell our products commercially, or may have other implications that significantly affect our commercialization and development efforts and general ability to conduct our business operations as planned. For example, government directed use of our products under such a program may result in our Cue Readers not being placed in settings where they will be used often for additional tests following the COVID-19 pandemic, which would adversely affect our long-term commercial plan that is based on increasing our installed base to roll out additional tests for use on the Cue Health Monitoring System. In addition, such government requirements may adversely affect our regular operations and financial results, result in differential treatment of customers and/or adversely affect our reputation and customer relationships. It is also possible that any change in the current administration could impact the manner in which the government uses the DPA and its other authorities, and result in additional or different risk to us.

The COVID-19 pandemic could materially adversely affect our business, financial condition and results of operations.

Like other companies, our business has been and will continue to be affected by the COVID-19 pandemic. For example, the spread of COVID-19 has caused us to modify our business practices (including on-site employee and visitor testing, employee travel, employee work locations, and the cancellation of physical participation in meetings, events and conferences) and delay our clinical study for our influenza test. We started our external influenza clinical study in January 2020. The study utilized a number of sites throughout the country. Many of these sites were research facilities that focused on clinical studies and do not provide clinical care. When the COVID-19 pandemic began spreading in the United States in early February and March 2020, many of these facilities began preventing potential enrollees from entering the sites if they exhibited any respiratory disease symptoms. This significantly impacted the enrollment of participants in our influenza test studies. We subsequently chose to pause, and ultimately stop, the study

due to very low enrollment. Future planned clinical studies may also be postponed due to low infection prevalence and/or the shuttering of research facilities where clinical studies are conducted. Postponement of such studies may delay us from completing development and seeking regulatory clearances or approvals for our tests currently in development and future products. We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, consumers and partners. The degree to which COVID-19 will impact our business and operations going forward is unknown and will depend on future developments, which are highly uncertain and cannot be predicted, including, but not limited to, the continued duration and spread of the outbreak, the emergence of novel variants, the degree of severity of the outbreak and existing and new variants, the development and administration of existing and new therapeutic treatments and vaccines, the actions taken by national, regional, and local governments and health officials to contain the virus or treat its impact, how quickly and to what extent normal economic and operating conditions can resume, whether the supply of components and raw materials will remain sufficient to satisfy demand and any impact on its pricing, and whether any of our third-party manufacturers experience any business interruptions which result in the delay of delivery of our products or components. Even after the outbreak of COVID-19 has subsided, we may experience material impacts to our business as a result of its global economic impact, including any recession or other negative widespread economic impacts that may occur as a result of the pandemic.

If we were to be sued for product liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of the Cue Health Monitoring System and any of our current and future tests and products could lead to the filing of product liability claims where someone may allege that the Cue Health Monitoring System identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. In addition, we may be subject to product liability claims resulting from misuse or off-label use of the Cue Health Monitoring System. See the risk factor titled "—The misuse or off-label use of our tests may harm our reputation or the image of our tests in the marketplace, or result in injuries that lead to product liability suits, which could be costly to our business. Moreover, we could be subject to FDA sanctions if we are deemed to have engaged in off-label promotion." A product liability claim could result in substantial damages and be costly and time-consuming for us to defend. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to continue commercializing the Cue Health Monitoring System or other new products;
- decreased demand for our Cue Readers or Cue Test Kits;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants;
- loss of sales; or
- termination of existing agreements by our partners and potential partners failing to partner with us.

We maintain product liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of any component of the Cue Health Monitoring System may delay the supply of those components to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation

for safety or be perceived by patients as a safety risk when considering the use of our tests, either of which could negatively affect our business, financial condition and results of operations.

Current or future litigation, government investigations and other legal proceedings may harm our business.

We have been, currently are and may in the future become, involved in legal proceedings that could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. The types of legal proceedings we may be or become subject to include patent and other intellectual property claims, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions, and other legal proceedings, investigations or claims. For example, in February 2018, the staff of the SEC's Division of Enforcement issued a subpoena to us requesting certain documents and information and we have been cooperating fully with the SEC's investigation. Litigation and other legal proceedings are inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for any of our products or other offerings under our Cue Integrated Care Platform, even if the regulatory or legal action is unfounded or not material to our operations. For additional information, see the section titled "Business—Legal Proceedings."

We depend on our information systems and those of third parties for the effective and efficient functioning of our business.

We depend on our information systems for the effective and efficient functioning of our business, including the manufacture, distribution and maintenance of the components of the Cue Health Monitoring System, as well as for accounting, data storage, compliance, purchasing and inventory management. Our information systems and those of third parties upon whom we rely may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions and other cyber-attacks. We could be subject to an unintentional event that involves a third-party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in the release of our confidential information. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. Third parties upon whom we rely or with whom we have business relationships, including our customers, collaborators, suppliers, and others, are subject to similar risks that could potentially have an adverse effect on our business.

Technological interruptions could disrupt our operations, including our manufacturing operations, our ability to timely ship and track product orders, our ability to manage project inventory requirements, our ability to manage our supply chain and our ability to otherwise adequately service our customers or disrupt our customers' ability use the Cue Health Monitoring System or the Cue Integrated Care Platform.

In the event we experience significant disruptions in our information systems, we may be unable to address such disruptions in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and harm our business, financial condition and results of operations. Any business interruption insurance carried by us may not be sufficient to protect us against any such business disruptions. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could harm our business, financial condition and results of operations.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business, or information of our customers, users of our products, healthcare stakeholders or others, or prevent us or our customers, users of our products, healthcare providers, healthcare payors or others from accessing critical information, all of which could result in a material adverse effect, including without limitation, a material operational or service interruption, harm to our reputation, significant fines, penalties and liability, breach or triggering of Data Protection Laws, Privacy Policies and Data Protection Obligations, loss of customers or sales, or customers curtailing or ceasing their use of our services.

In the ordinary course of our business, we and our third-party service providers will collect, use, generate, transfer, and disclose, or Process, sensitive data, including legally protected health information, or PHI, and medical information, personally identifiable information, intellectual property and proprietary business information owned or controlled by us or our customers. In addition, we offer online customer-facing portals accessible through private and web portals. It is critical that we Process sensitive data in a secure manner to maintain the confidentiality and integrity of such confidential information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. These applications and related data encompass a wide variety of business-critical information including research and development information, commercial and financial information.

Although we take measures designed to protect such information from unauthorized access, use or disclosure, our information technology and infrastructure, and that of our third-party service providers may be vulnerable to natural disasters, war, terrorism, telecommunications and electrical failures, ransomware, nation-state attacks, social engineering, denial-of-service attacks, phishing attacks, cyber-criminals, cyber-attacks by hackers or viruses, or breaches due to employee error, malfeasance or other disruptions. We also face the ongoing challenge of managing access controls to our information technology systems. If we do not successfully manage these access controls it further exposes us to risk of security breaches or disruptions. Any such security breaches or disruptions could compromise the security or integrity of our networks or result in the loss, misappropriation, and/or unauthorized access, use, modification or disclosure of, or the prevention of access to, sensitive data or confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information). For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. If our or our vendors' information systems are breached, sensitive data are compromised, surreptitiously modified, rendered inaccessible for any period of time or maliciously made public, or if we fail to make adequate or timely disclosures to affected individuals, appropriate state and federal regulatory authorities or law enforcement agencies, if appropriate, following any such event, whether due to delayed discovery or a failure to follow existing protocols, it could result in significant fines, penalties, orders, sanctions and proceedings or actions against us by governmental bodies or other regulatory authorities, customers or third parties. Any of the foregoing could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects.

Cyber-attacks are increasing in frequency and evolving in nature, and this activity has increased even further during the COVID-19 pandemic. We are at risk of attack by a variety of adversaries, including state-sponsored organizations, organized crime, hackers or "hactivists" (activist hackers), through the use of increasingly sophisticated methods of attack, including long-term, persistent attacks referred to as advanced persistent threats. The techniques used to obtain unauthorized access or sabotage systems include, among other things, computer viruses, malicious or destructive code, ransomware, social engineering attacks (including phishing and impersonation), hacking and denial-of-service attacks. Our systems are also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, vendors and other third parties with otherwise legitimate access to our systems. Third parties may also attempt to fraudulently induce our employees and contractors into disclosing sensitive information such as user names, passwords, or other information or otherwise compromise the security of our electronic systems, networks, and/or physical facilities in order to gain access to our data. Additionally, due to the COVID-19 pandemic, our employees are temporarily working remotely, which may pose additional data security risks. Given the unpredictability of the timing, nature and scope of information technology disruptions, there can be no assurance that any security procedures and controls that we or our third-party service providers have implemented will be sufficient to prevent cyber-attacks from occurring. The latency of a compromise is often measured in months, but could be years, and we may not be able to detect a compromise in a timely

manner. New techniques may not be identified until they are launched against a target, and we may be unable to anticipate these techniques or detect an incident, assess its severity or impact, react or appropriately respond in a timely manner or implement adequate preventative measures, resulting in potential data loss or other damage to our information technology systems.

As the breadth and complexity of the technologies we use and the software and platforms we develop continue to grow, the potential risk of security breaches and cyber-attacks also increases. Our policies, employee training (including phishing prevention training), procedures and technical safeguards may be insufficient to prevent or detect improper access to confidential, proprietary or sensitive data, including personal data. In addition, the competition for talent in the data privacy and cybersecurity space is intense, and we may be unable to hire, develop or retain suitable talent capable of adequately detecting, mitigating or remediating these risks. As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business. Additionally, federal, state, local, and international laws, rules, regulations, guidance and opinions regarding privacy and information security, or collectively, Data Protection Laws, external and internal privacy and security policies, representations, certifications, standards, publications and frameworks, or collectively, Privacy Policies, and contractual obligations to third parties related to privacy and information security, or collectively, Data Protection Obligations, may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches, which may be costly or difficult to implement without adversely affecting our operations.

We expect that we may have numerous vendors and other third parties who receive personal data from us in connection with the products we offer our customers. In addition, we have migrated certain data, and may increasingly migrate data, to a cloud hosted by third-party vendors. Some of these vendors and third parties also have direct access to our systems. Due to applicable Data Protection Laws and Data Protection Obligations, we may be held responsible for any information security failure or cyber-attack attributed to our vendors as they relate to the information we share with them. In addition, because we do not control our vendors and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect confidential, proprietary, or sensitive data, including personal data, or prevent cyber-attackers from gaining access to our infrastructure or data through our vendors or other third parties.

Regardless of whether an actual or perceived cyber-attack is attributable to us or our third-party service providers, such an incident could, among other things, result in improper disclosure of information, harm our reputation and brand, reduce the demand for our products, lead to loss of customer confidence in the effectiveness of our security measures, disrupt normal business operations or result in our systems or products being unavailable. In addition, it may require us to spend material resources to investigate or correct the breach and to prevent future security breaches and incidents. The costs related to significant security breaches or disruptions could be material and exceed the limits of any cybersecurity insurance we maintain, increase our risk of regulatory scrutiny, expose us to legal liabilities, including litigation, regulatory enforcement, indemnity obligations or damages for contract breach, divert the attention of management from the operation of our business and cause us to incur significant costs, any of which could affect our financial condition, operating results and our reputation. Moreover, there could be public announcements regarding any such incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. In addition, our remediation efforts may not be successful. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

We may not have adequate insurance coverage to protect us against the various types of business risks we face.

We may not have adequate insurance coverage to protect us against the various types of business risks we face. This includes risks such as product liability risk, business interruption risk and other risks we may face. The successful assertion of one or more large claims against us that exceeds our available insurance coverage or for which we are self-insured, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside the United States.

An element of our business strategy is to market our products outside the United States, if cleared, authorized or approved. Currently, we have a CE mark in the European Union, as well as Interim Order authorization from Health Canada, which is the department of the Government of Canada responsible for national health policy, for our COVID-19 test. In June 2021, our COVID-19 test also received regulatory approval from the CDSCO for professional point-of-care use in India. We expect to seek further authorizations, clearances and approvals outside of the United States. As a result, we expect that our business will be subject to risks associated with doing business outside the United States, including an increase in our expenses and diversion of our management's attention from other aspects of our business. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- failure by us or our distributors to obtain regulatory clearance, authorization or approval for the use of our products in various countries and other jurisdictions;
- multiple, conflicting and changing laws and regulations such as privacy security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anti-corruption laws, regulatory requirements, reimbursement or payor regimes and other governmental approvals, permits and licenses;
- additional potentially relevant third-party patent rights;
- pricing pressures and differing reimbursement regimes;
- complexities and difficulties in obtaining intellectual property protection and maintaining, defending and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- employment risks related to hiring employees outside the United States;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- regulatory authorities revoking or terminating our authorizations and approvals in Canada, the European Union and India, or other jurisdictions;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- regulatory and compliance risks related to adherence with foreign privacy and data security laws, including the General Data Protection Regulation 2016/679 and other similar bodies of law;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions, or laws similar to the FCPA in other jurisdictions in which we may now or in the future operate, such as the United Kingdom's Bribery Act of 2010, or U.K. Bribery Act; and
- onerous anti-bribery requirements of several member states in the EU, the United Kingdom, and other countries that are constantly changing and require disclosure of information to which U.S. legal privilege may not extend.

Any of these factors or other risks associated with international operations could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We may acquire other businesses, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our results of operations.

We may in the future make acquisitions or investments in complementary companies, technologies or products that we believe fit within our business model and can address the needs of our customers and potential customers. We may not be able to integrate any acquired companies, technologies or products in a successful manner. In addition, we may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. The pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, including increases in revenue, and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts.

Future acquisitions may reduce our cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition or the value of our common stock. The sale or issuance of equity to finance any such acquisitions would result in dilution to our stockholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include covenants or other restrictions that could impede our ability to manage our operations. In addition, our future results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition. Furthermore, acquisitions may require large, onetime charges and can result in increased debt or contingent liabilities, adverse tax consequences, additional stock-based compensation expenses and the recording and subsequent amortization of amounts related to certain purchased intangible assets, any of which items could negatively affect our future results of operations. We may also incur goodwill impairment charges in the future if we do not realize the expected value of any such acquisitions.

We may not realize the intended benefits of any acquisition we may make. To the extent we pursue any strategic alliances or joint ventures, we may similarly fail to realize the intended benefits of any such transaction.

Risks Related to Our Financial Condition and Capital Requirements

We may in the future consider raising additional capital for any number of reasons, including to fund our operations, further develop our Cue Integrated Care Platform, develop and commercialize new tests and products, and expand our operations.

We may in the future consider raising additional capital for any number of reasons and to do so, we may seek to sell common or preferred equity or convertible debt securities, enter into one or more credit facilities or another form of third-party funding, or seek other debt financing. We may also need to raise capital sooner or in larger

amounts than we anticipate for numerous reasons, including because of lower demand for our COVID-19 test, the cancellation of any of our contracts with our largest customers, through no fault of our own, or as a result of failure to obtain regulatory approvals for our other tests, or other risks described in this prospectus.

We may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- increase our sales and marketing efforts to facilitate market adoption of our products and address competitive developments;
- fund development and marketing efforts of any future products;
- further expand our operations outside the United States;
- acquire, license or invest in technologies, including information technologies;
- satisfy any outstanding or future debt obligations;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to successfully commercialize the Cue Health Monitoring System, including our COVID-19 test;
- the costs of the sales and marketing activities associated with commercializing the Cue Health Monitoring System, including our COVID-19 test;
- the length of the COVID-19 pandemic;
- our ability to secure and maintain domestic and international regulatory authorization, clearance or approval for our products;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- our ability to control our manufacturing and operating costs;
- our ability to satisfy any outstanding or future debt obligations;
- the effect of competing technological and market developments;
- litigation expenses we incur to defend against claims that we infringe the intellectual property of others or judgments we must pay to satisfy such claims;
- the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products; and
- the costs of responding to the other risks and uncertainties described in this prospectus.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, our stockholders' ownership interests will be diluted. Any equity securities we issue could also provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock.

Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and ability to continue operating as a going concern.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including a reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses, or NOLs, arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, the elimination of U.S. tax on foreign earnings (subject to certain important exceptions), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal of many business deductions and credits.

As part of Congress's response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or the FFCR Act, was enacted on March 18, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted on March 27, 2020, and COVID relief provisions were included in the Consolidated Appropriations Act, 2021, or CAA, which was enacted on December 27, 2020. All contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80% of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017 and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act, and the CAA is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. Congress may enact additional legislation in connection with the COVID-19 pandemic, and, as a result of the changes in the U.S. presidential administration and control of the U.S. Senate, additional tax legislation may also be enacted, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act, the CARES Act, or the CAA.

Our ability to use our net operating losses, or NOLs, and certain other tax attributes to offset future taxable income is subject to certain limitations.

As of December 31, 2020, we had federal and state NOL carryforwards of approximately $108.7 million and $90.8 million, respectively. The federal NOLs include $26.2 million that may be used to offset up to one hundred percent (100%) of future taxable income. The federal and state NOLs, if unused, will begin to expire in calendar year 2031. The NOL carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities.

In general, under Sections 382 and 383 of the Code and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have conducted a study and determined that, through December 31, 2020, such ownership changes occurred in 2014 and 2018. Accordingly, our ability to use certain of our NOLs and other tax attributes to offset our taxable income is limited by Sections 382 and 383. We may also experience such ownership changes in the future as a result of this offering and/or subsequent changes in our stock ownership (which may be outside our control). As a result, our ability to use our pre-change NOLs and other tax attributes to offset taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition," the TCJA, as amended by the CARES Act, includes changes to U.S. federal tax

rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, for state income tax purposes, there may be period during which the use of NOLs is suspended or otherwise limited, such as recent California legislation limiting the usability of NOLs for tax years beginning after 2019 and before 2023. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, we may be unable to use a material portion of our NOLs and other tax attributes.

Our business may be subject to additional obligations to collect and remit sales tax and other taxes, and we may be subject to tax liability for past sales.

Any successful action by state, foreign (if we start selling internationally) or other authorities to collect additional or past sales tax could harm our business. States and various local taxing jurisdictions have differing rules and regulations governing sales and use taxes, and these rules and regulations are subject to varying interpretations that may change over time. It is possible that we could face sales tax audits and that our liability for these taxes could exceed our estimates as state tax authorities could assert that we are obligated to collect additional amounts as taxes from our customers and remit those taxes to those authorities. We could also be subject to audits in states and foreign jurisdictions (if we start selling internationally) for which we have not accrued tax liabilities. A successful assertion that we should be collecting additional sales or other taxes on our products in jurisdictions where we have not historically done so and do not accrue for sales taxes could result in substantial tax liabilities for past sales, discourage customers from purchasing our products or otherwise harm our business, financial condition and results of operations.

We file sales tax returns in certain states within the United States as required by law.

We file sales tax returns in certain states where we have been advised or have determined we have an obligation to do so, however, we do not collect sales or other similar taxes in all states, and one or more states (or foreign authorities if we start selling internationally) could seek to impose additional sales, use or other tax collection and record-keeping obligations on us or may determine that such taxes should have, but have not been, paid by us. Liability for past taxes may also include substantial interest and penalty charges. Any successful action by state, foreign or other authorities to compel us to collect and remit sales, use or other taxes, either retroactively, prospectively or both, could harm our business, financial condition and results of operations.

We hope to be a multinational organization, in which case we would be faced with increasingly complex tax issues in many jurisdictions, and we could be obligated to pay additional taxes in various jurisdictions.

If we become a multinational organization, we may be subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application of which can be uncertain. The amount of taxes we pay in these jurisdictions could increase substantially as a result of changes in the applicable tax principles, including increased tax rates, new tax laws or revised interpretations of existing tax laws and precedents, which could have a material adverse effect on our liquidity and results of operations. Furthermore, one or more jurisdictions in which we do not believe we are subject to tax payment, withholding or filing requirements could assert that we are subject to such requirements. Any of these claims or assertions could have a material impact on us and the results of our operations.

Risks Related to Manufacturing Our Products

We have limited experience manufacturing our products in commercial quantities; if we are unable to manufacture our products in the required quantities in a timely manner, our business could be materially adversely affected.

We have only limited experience in manufacturing our products in commercial quantities, and only first began commercializing the Cue Health Monitoring System in June 2020. We currently lease and operate three manufacturing facilities for the production of our Cue Cartridges: our Nancy Ridge facility, Vista facility and Waples facility. Given our limited commercial manufacturing experience and rapid ramp up of our manufacturing capabilities, we may be more susceptible to encountering production delays, interruptions or shortfalls than other companies with a longer track record of manufacturing products at commercial scale. Such production delays, interruptions or shortfalls may be caused by many factors, including the following:

- production issues that may arise out of the rapid expansion of our manufacturing capacity, including the opening of two new manufacturing facilities within the last 12 months;

- a setback in our anticipated timeline for finalizing the construction of our new production pods, which would result in manufacturing delays;
- key components of our products are provided by a single supplier or limited number of suppliers, and we do not maintain large inventory levels of these components such that, if we experience a shortage or quality issues in any of these components, we would need to identify and qualify new supply sources, which could increase our expenses and result in manufacturing delays;
- a delay in completing assembly of new controlled environment rooms at our manufacturing facility;
- state and federal regulations, including the FDA's Quality System Regulations, or QSR, for the manufacture of our products, noncompliance with which could cause an interruption in our manufacturing; and
- attraction and retention of qualified employees for our operations in order to significantly increase our manufacturing output.

We currently expect that customer demand for our COVID-19 test will exceed our manufacturing capacity in 2021. If we are unable to continue to keep up with demand for our products, our growth could be impaired, and market acceptance for our products and our reputation could be harmed and customers and other users of our products may instead elect to use our competitors' products. Our inability to successfully manufacture our products in sufficient quantities would materially harm our business.

In addition, our manufacturing facility and processes and those of our third-party suppliers are subject to unannounced FDA and state regulatory inspections for compliance with the QSR. Developing and maintaining a compliant quality system is time consuming and expensive. Failure to maintain compliance with, or not fully complying with the requirements of the FDA and state regulators, could result in enforcement actions against us or our third-party suppliers, which could include the issuance of warning letters, seizures, prohibitions on product sales, recalls and civil and criminal penalties, any one of which could significantly impact our manufacturing supply and impair our financial results.

If we, our suppliers or our contract manufacturers experience significant disruptions to our or their manufacturing capabilities or ability to source needed supplies and materials, our business may be materially adversely affected.

Our operations, or those of our suppliers or third-party contract manufacturers, could become subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, including the COVID-19 pandemic, and other natural or man-made disasters or business interruptions. Our corporate headquarters and manufacturing facilities are located in San Diego, California, near major earthquake faults and fire zones, and our suppliers and contract manufacturers may be subject to similar risks, whether due to earthquakes, fires or other natural disasters or business interruption risks. Our ability to obtain components for our Cue Cartridges would be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. In addition, we rely on third party contract manufacturers for the manufacture of our Cue Readers and for some of the production of our Cue Wands. The occurrence of any type of business disruption at any of our own facilities or those of our suppliers or contract manufacturers could materially harm our operations, financial condition and results of operations, as well as otherwise have a material adverse effect on our business. While we maintain business interruption insurance to protect us from some of these risks, such insurance may not cover us for all business interruption risks we face and, even where we do have coverage, such coverage may not be sufficient in amount.

Over time, we may add new manufacturing facilities or relocate manufacturing to one more additional facilities, which may include additional facilities located elsewhere within or outside of the United States. The use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval. Because of the time required to authorize manufacturing in a new facility under FDA and non-U.S. regulatory requirements, we may not be able to commence production at such a facility on a timely basis. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause us to be unable to meet customer demand, cause customers and other users of our products to discontinue using the Cue Health Monitoring System, or harm our reputation, and we may be unable to reestablish relationships with such customers and users in the future.

We contract with third parties for the manufacture of our Cue Readers, Cue Wands and certain other components of the Cue Health Monitoring System. This reliance on third parties increases the risk that we will not have sufficient quantities of our Cue Health Monitoring System or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

While we manufacture all of our Cue Cartridges in our own manufacturing facilities, we rely, and expect to continue to rely, on third parties for the manufacture of our Cue Readers, Cue Wands and Cue Control Swab Packs. This reliance on third parties increases the risk that we will not have sufficient quantities of our Cue Readers, Cue Wands or quality control swabs that are included in our Cue Control Swab Packs or, ultimately, of our Cue Health Monitoring System or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

During the duration of our EUAs for our COVID-19 test, the FDA has waived certain current good manufacturing practices, or cGMP, requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of our COVID-19 test but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 280.90), and Subpart O (Statistical Techniques, 21 CFR 820.250). This means that our third-party manufacturing facilities will not need to, and may not, be compliant with all of the FDA's cGMPs. To the extent that we no longer have an EUA and need to seek FDA authorization for our COVID-19 test, we need to comply with cGMPs which may cause delays in production at our and our third-party manufacturing facilities.

In addition, while we audit and monitor our contract manufacturers to ensure they meet our contracted specifications, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with the manufacture of our products or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to produce or market our COVID-19 tests and any future contemplated tests, if authorized for commercialization by the relevant regulatory agency.

If any contract manufacturing organization, or CMO, with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our Cue Health Monitoring System supply could be delayed significantly as we establish alternative supply sources for components of our Cue Health Monitoring System, such as Cue Readers or Cue Wands. In some cases, the technical skills required to manufacture our product components may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product components according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop products or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our products that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior contract manufacturing organization used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating comparability which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals or authorizations, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products.

We may be unable to establish any additional agreements with third-party manufacturers or do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;

- the possible delay or stoppage in production of certain components of the Cue Health Monitoring System that delays shipments of Cue Readers or Cue Test Kits to our customers;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any products that we may develop may compete with our other products for access to manufacturing facilities.

Any performance failure on the part of our existing or future manufacturers could delay production and cause us to miss certain production targets. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Our suppliers may fail to deliver components according to schedules, prices, quality and volumes that are acceptable to us, or we may be unable to manage these components effectively.

Our products contain components and raw materials that we purchase globally from mostly single-source direct suppliers, generally without long-term supply agreements. This exposes us to multiple potential sources of component shortages. Unexpected changes in business conditions, materials pricing, labor issues, wars, governmental changes, tariffs, natural disasters, health epidemics such as the global COVID-19 pandemic, trade and shipping disruptions and other factors beyond our or our suppliers' control could also affect these suppliers' ability to deliver components to us or to remain solvent and operational. For example, a global shortage of microchips has been reported since early 2021. The semiconductor supply chain is complex and has historically been characterized by wide fluctuations in the demand for, and supply of, its products. These fluctuations have resulted in circumstances where supply of and demand for semiconductors has been widely out of balance. Wafer foundries that support chipmakers have not invested enough in recent years to increase capacities to the levels needed to support demand from all of their customers. Wafers have a long lead time for production which further exacerbates the shortage. The full extent to which this global shortage might impact us is not yet known. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products. Moreover, our ramp up in production of our Cue Cartridges, or product design changes by us have required and may in the future require us to procure additional components in a short amount of time. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. Finally, we have limited manufacturing experience outside of our Nancy Ridge manufacturing facility and we may experience supply chain and procurement issues at the Nancy Ridge Facility as well as at our new Vista and Waples facilities. While we believe that we will be able to secure additional or alternate sources or develop our own replacements for most of our components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be unsuccessful in our continuous efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain components and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

As the scale of our Cue Health Monitoring System production increases, we will also need to accurately forecast, purchase, warehouse and transport components and raw materials at high volumes to our own and our third-party manufacturing facilities and servicing locations, which includes locations in the U.S. and China. If we are unable to accurately match the timing and quantities of component purchases to our actual needs or successfully implement automation, inventory management and other systems to accommodate the increased complexity in our supply chain and parts management, we may incur unexpected production disruption, storage, transportation and write-off costs, which may harm our business and operating results.

Risks Related to Our Intellectual Property

Our patent or other intellectual property protection for the Cue Health Monitoring System, products and Cue Integrated Care Platform may not be sufficient to prevent competitors from developing and commercializing tests and platforms similar to or otherwise comparable to our Cue Test Kits, products and Cue Integrated Care Platform, which could materially adversely affect our business and prospects.

As with other diagnostic testing companies, our success depends in large part on our ability to obtain, maintain and solidify a proprietary position for our Cue Integrated Care Platform and our current and any future tests, which will depend upon our success in obtaining effective patent protection and other intellectual property, in the United States and other countries, with respect to, such tests, their manufacturing processes and their intended methods of use, as well as enforcing those patent claims once granted and other intellectual property rights. In some cases, we may not be able to obtain issued patent claims or other registered intellectual property covering various aspects of our technologies which are sufficient to prevent third parties, such as our competitors, from utilizing our Cue Integrated Care Platform. Any failure to obtain or maintain patent and other intellectual property protection with respect to our Cue Integrated Care Platform or our current and any future tests or other aspects of our business could harm our business, financial condition and results of operations.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions.

Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, and are therefore reliant on our licensors or licensees, and may be reliant on future licensors or licensees, to protect certain of our intellectual property used in our business. If such licensors or licensees fail to adequately protect this intellectual property or if we do not have exclusivity for the marketing of our tests, whether because our licensors do not grant us exclusivity or they do not enforce the intellectual property against our competitors, our ability to commercialize products could suffer.

Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any current or future licensors or licensees fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If any current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may materially harm our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to changes to statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents or the chances that patent applications will result in issued claims and the scope of any such claims. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our current and any future tests. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of the Cue Health Monitoring System or our current and any future tests, which may harm our business. Furthermore, even if they are unchallenged, our patents may not adequately protect the Cue Health Monitoring System or our current and any future tests, provide exclusivity for our Cue Integrated Care Platform or such current or future tests or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and tests would be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our current and any future tests is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, the Cue Health Monitoring System and our current and any future tests.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for the components of our Cue Health Monitoring System, we may be open to competition, which may harm our business prospects. Further, if we encounter delays in our development efforts, the period of time during which we could market the Cue Health Monitoring System under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future tests, patents protecting our current and any future tests might expire before or shortly after such tests are commercialized. For information regarding the expiration dates of patents in our patent portfolio, see the section titled “Business—Intellectual Property.” As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing platforms or tests similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own now or in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our current and any future tests or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or tests in a non-infringing manner which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may in the future be jointly-owned with third parties. If we are unable to obtain an exclusive license to any such third-party joint-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing platforms or tests and technology. In addition, we may need the cooperation of any such joint-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

We have obtained license or service agreements from certain third-party intellectual property holders. If we breach our agreements, it could have a material adverse effect on our commercialization efforts for the Cue Health

Monitoring System or our current and any future tests and services. Further, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our current and any future tests. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant tests, which could harm our business, financial condition and results of operations.

Patents covering our current, and any future tests, the Cue Health Monitoring System, or our technologies could be challenged by third parties. If our patents are found to be invalid or unenforceable, our business could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad and may not provide us with adequate proprietary protection or competitive advantage against competitors with similar products. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allowing third parties to commercialize the Cue Health Monitoring System or our current and any future tests and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize the Cue Health Monitoring System or any current or future tests without infringing third-party patent rights. Moreover, we may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and tests, or limit the duration of the patent protection of the Cue Health Monitoring System or our current and any future tests or technologies. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third-party to enforce a patent covering the Cue Health Monitoring System or our current and any future tests, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover the Cue Health Monitoring System, our current and any future tests or technologies. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or other third-party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the Cue Health Monitoring System, our current and any future tests and technology. Such a loss of patent protection would harm our business, financial condition and results of operations.

We rely substantially on our trademarks and trade names. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.

We rely substantially upon trademarks to build and maintain the integrity of our brand. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared unenforceable or determined to be violating or infringing on other intellectual property rights. We may not be able to protect or enforce our rights to these trademarks and trade names, which we rely upon to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Asserting claims against such third parties may be prohibitively expensive. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks against us. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could harm our business, financial condition and results of operations.

The diagnostic testing industry is characterized by intellectual property litigation and in the future we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing the Cue Health Monitoring System or our existing or future tests.

Litigation regarding patents, trademarks, trade secrets, and other intellectual property rights is prevalent in the medical device and diagnostic sectors and companies in these sectors have used intellectual property litigation to gain a competitive advantage. Our commercial success depends in part upon our ability and that of our contract manufacturers and suppliers to manufacture, market, and sell our planned tests, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. Because we have not conducted a comprehensive freedom to operate analysis for patents related to the Cue Health Monitoring System or our tests, we may not be aware of issued patents that a third-party, including a competitor, might assert are infringed by the Cue Health Monitoring System or our current or any future tests, which could materially impair our ability to commercialize the Cue Health Monitoring System or our current or any future tests. Even if we diligently search third-party patents for potential infringement by the Cue Health Monitoring System or our current or any future tests, we may not successfully identify patents that the Cue Health Monitoring System or our current or any future tests may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing the Cue Health Monitoring System or our current or future tests. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future tests and technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. Like other companies operating in the diagnostic testing space, we have, from time to time, received demand letters from third parties claiming that our business allegedly infringes their patents; however, in each case we have investigated the alleged claims and, in our responses to the claimants, have disputed their allegations as lacking any merit, and to date, no legal proceeding has ever been initiated by such third parties. In addition, while we have not conducted a comprehensive freedom to operate analysis, we are aware of patent claims that could be alleged to cover the methodology and compositions used by the Cue Health Monitoring System. While we believe that the patent claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. In the future, other third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing the Cue Health Monitoring System, our current and any future tests and technology. We may also elect to enter into such a license to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or tests. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned tests in commercially important territories, or force us to cease some of our business operations, which could harm our business. A number of our employees were or may have been

previously employed at, and a number of our current advisors and consultants are employed or may be employed by, universities or other biotechnology, medical device or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.

Obtaining and maintaining our intellectual property, including patent, protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government agencies, and our intellectual property, including patent, protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining our intellectual property, including patent, protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government agencies, and our intellectual property, including patent, protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on intellectual property registrations and applications will be due to be paid to the applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, over the lifetime of our intellectual property registrations and applications, including our patents and patent applications. The various applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, require compliance with several procedural, documentary, fee payment and other similar provisions during the application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the intellectual property registration or application, resulting in a partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of an intellectual property registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical platforms, tests or technology, which could harm our business, financial condition and results of operations.

We have foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents or trademarks on the Cue Health Monitoring System, Cue Virtual Care Delivery Apps, Cue Data and Innovation

Layer and our current and any future tests in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Consequently, we may not be able to prevent third parties from practicing our inventions or utilizing our trademarks in all countries outside the United States, or from selling or importing the Cue Health Monitoring System or tests made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own platforms or tests and, further, may export otherwise infringing platforms or tests to territories where we have patent protection but enforcement is not as strong as that in the United States. These platforms and tests may compete with the Cue Health Monitoring System or our current and any future tests, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing tests in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect the Cue Health Monitoring System or our current and any future tests.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to the Cue Health Monitoring System or our current and any future tests.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have made and will likely continue to make changes in how the patent laws of the United States are interpreted. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

We may be subject to claims challenging the ownership or inventorship of our patents and other intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our current and any future tests.

We may be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our current and any future tests. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our current and any future tests. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our current and any future tests. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and tests. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition and results of operations.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of Cue Health Monitoring Systems.

The diagnostic testing industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights.

Our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell the Cue Health Monitoring System, including any tests that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the point-of-care and at-home over-the-counter molecular diagnostic testing field, and such third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of the Cue Health Monitoring System or our current and any future tests infringes upon these patents. Although no third party has initiated any legal proceedings asserting a claim of patent infringement against us as of the date of this registration statement, third parties may hold proprietary rights that could prevent the manufacture, use or sale of the Cue Health Monitoring System. For example, while we have not conducted a comprehensive freedom to operate analysis, we are

aware of patent claims that could be alleged to cover the methodology and compositions used by the Cue Health Monitoring System. While we believe that the patent claims may not be valid and that they may be reasonably challenged for validity, there can be no assurance that any such challenge would be successful. Beyond the foregoing potential conflicts, we have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and can give no assurance that other patents containing claims covering the Cue Health Monitoring System or our current and any future tests, parts of the Cue Health Monitoring System or our current and any future tests, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which the Cue Health Monitoring System or our current or future tests infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by the Cue Health Monitoring System or our current and any future tests, which could harm our ability to commercialize the Cue Health Monitoring System or any test we may develop and any other technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the Cue Health Monitoring System, the applicable tests or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize the Cue Health Monitoring System or our current and any future tests, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the Cue Health Monitoring System, the infringing tests and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign the Cue Health Monitoring System, our infringing tests or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or the patents of any future licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of any such licensing partners also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Any of the foregoing could harm our business, financial condition and results of operations.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition and results of operations.

As is common in the diagnostic testing industry, our employees, consultants and advisors may be currently or previously employed or engaged at universities or other medical device, healthcare and technology companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these people have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. Also, we may in the future be subject to claims that these people are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make systems or tests that are similar to the Cue Health Monitoring System or our current and any future tests or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in the Cue Health Monitoring System or our current and any future tests that is in the public domain;
- we, or our current and future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current and future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our current and any future test or technology similar to ours;
- it is possible that our patents or patent applications omit people that should be listed as inventors or include people that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- the claims of our patents or patent applications, if and when issued, may not cover our current and any future tests or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop test or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive platforms or tests for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing platforms or tests that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition and results of operations.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for the Cue Health Monitoring System and our current and any future tests, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets and know-how can be difficult to protect. We seek to protect such proprietary information, in part, through non-disclosure and confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have

agreements with our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third-party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these people, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could harm our business, financial condition and results of operations.

Risks Related to Government Regulation and Our Industry

We received two EUAs and intend to seek additional and/or amended EUAs for our COVID-19 test. The FDA may not timely grant any additional or amended EUAs, if at all. For our existing EUAs and any new EUA, the FDA may revoke any EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, which would adversely impact our ability to market our COVID-19 test in the United States.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved and available alternatives. On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services, or U.S. HHS, issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, U.S. HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to development of in vitro diagnostic tests during the COVID-19 public health emergency. This guidance was updated on March 16, 2020, May 4, 2020 and May 11, 2020. It is uncertain whether the widespread availability of approved and effective vaccinations could expedite or influence any such decision making with respect to the underlying health emergency.

The speed at which companies and institutions are acting to create and test medical products for COVID-19 is unusually rapid, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 test. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed clinical trials with minimal lead time.

On June 10, 2020, we received an EUA from the FDA for our COVID-19 test for use at the point-of-care with specimens collected using the Cue Wand from individuals who are suspected of having COVID-19 by their healthcare provider. On August 20, 2020, the FDA granted an amendment to our EUA to add testing of previously collected nasal specimens in viral transport media from individuals who are suspected of having COVID-19 by their healthcare

provider. On March 5, 2021, we received an EUA for our COVID-19 test for home and over-the-counter use by individuals aged two years or older with or without symptoms or other epidemiological reasons to suspect COVID-19 and without a prescription. We cannot predict how long the EUAs for our COVID-19 test will remain in place.

There can be no assurances that the FDA will authorize any request for additional and/or amended EUAs and if we do not receive the authorization, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Because the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, we cannot predict how long our EUAs will remain in place. The FDA may also revoke an EUA when the circumstances justifying its issuance no longer exist, such as when an alternative is authorized for marketing through the standard procedures, such as through a 510(k) clearance. The FDA has stated that, given the magnitude of the COVID-19 health crisis and the testing capacity challenges in the United States, it has no intention of terminating EUAs for COVID-19 diagnostic tests based solely on a test receiving 510(k) clearance. However, the FDA may change this position at any time and without notice.

FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence. Changes to FDA regulations or requirements could require changes to our authorized test, necessitate additional measures, or make it impractical or impossible for us to market our test. The revocation of an EUA, if granted, could necessitate that we pursue the lengthy and expensive 510(k) clearance process, if available, or another similarly burdensome marketing authorization process, such as a de novo classification. Indeed, FDA has recommended that manufacturers of tests subject to an EUA pursue pre-market submissions such as a 510(k), de novo classification, or pre-market approval, or PMA, as applicable, during the declared public health emergency so that their devices can remain on the market after the emergency terminates. As a result, any such revocation could adversely impact our business, financial condition and results of operations.

If the FDA revokes either of our existing EUAs prior to us having received regulatory approval to commercialize our COVID-19 test through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business.

The Cue Health Monitoring System and our current and future tests require marketing authorizations, clearances or approvals from regulatory agencies before they can be marketed. Any such regulatory process would be expensive, time-consuming and uncertain both in timing and in outcome. If we fail to obtain or maintain necessary marketing authorizations, clearance, or approval, or if such authorizations, clearances or approvals for future products are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

While we received two EUAs for our COVID-19 test, our strategy is to expand our product line to encompass products that are intended to be used at the point-of-care and at-home. Such products will be subject to regulation by the FDA as medical devices, including requirements for regulatory authorization, clearance or approval of such products before they can be marketed. Accordingly, we will be required to obtain marketing authorization, clearance, or approval, in order to sell our future products in a manner consistent with FDA laws and regulations. Such processes are expensive, time-consuming and uncertain; our efforts may never result in any marketing authorization, clearance, or approval; and failure by us to obtain or comply with such marketing authorizations, clearances or approvals could have an adverse effect on our business, financial condition or operating results. The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the United States, before we can market a new medical device, or a new use of, or claim for, an existing product, we must first receive either 510(k) clearance, PMA approval or approval of a de novo application from the FDA, unless an exemption applies. The FDA also has authority to issue EUAs in times of crises such as pandemics (declaration of emergencies), which the FDA granted us for our COVID-19 test.

In the United States, outside of the context of the EUA application process, our tests will likely need to obtain clearance through the 510(k) premarket notification process. If the FDA requires us to go through a lengthier, more rigorous process for future products or modifications to existing products than expected, our product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we do not

currently market any devices under a PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. Further, even with respect to those future products where a PMA is not required, we may not be able to obtain the 510(k) clearances with respect to those products. The FDA can delay, limit or deny 510(k) clearance or PMA approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our tests are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- the manufacturing process or facilities we use or contract to use may not meet applicable requirements; and
- disruptions at the FDA caused by funding shortages or global health concerns, including the COVID-19 pandemic.

The FDA may refuse our requests for 510(k) clearance, de novo or PMA of new products, new intended uses or modifications to existing products.

From time to time, legislation is drafted and introduced in the United States that could significantly change the statutory provisions governing any regulatory approval or clearance that we receive in the United States. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our tests under development or impact our ability to modify our currently approved or cleared tests on a timely basis.

Modifications to our Cue Health Monitoring System and any current or future tests may require new regulatory authorizations, clearances or approvals or may require us to recall or cease marketing our Cue Health Monitoring System or any current or future tests until authorizations, clearances or approvals are obtained.

Once our Cue Health Monitoring System or any current or future tests are initially authorized, cleared or approved, modifications to such products may require new regulatory authorizations, approvals or clearances, including additional EUAs, 510(k) clearances or PMA approvals, or require us to recall or cease marketing the modified devices until these authorizations, clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new authorization, approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We may make modifications to our tests in the future. For example, we are developing additional software component to our tests, which may require new clearances or approvals from the FDA. If the FDA requires new authorizations, clearances or approvals for the modifications, we may be required to recall and to stop marketing our tests, as approved and as modified, which could require us to redesign our tests and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA 510(k)-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a PMA application. Where we determine that modifications to our products require a new 510(k) clearance or PMA, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining authorizations, clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced tests in a timely manner, which in turn would harm our future growth.

We require a waived designation under the Clinical Laboratory Improvement Amendments of 1988 from the FDA for our products to be used at the point-of-care, and outside of the clinical laboratory setting.

A Clinical Laboratory Improvement Amendments of 1988, or CLIA,-waived designation by the FDA is required for our products to be used at the point-of-care, and outside of the clinical laboratory setting but is not required for our at-home and over-the-counter COVID-19 test. We are subject to CLIA and its implementing regulations in the United States which establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results

regardless of where the test is performed. Laboratory tests regulated under CLIA are categorized by the FDA as waived, moderate complexity or high complexity based on set criteria. Tests that are waived by regulation, or cleared, approved, or otherwise authorized by the FDA for home use or a point-of-care test, are deemed waived following marketing authorization. Our COVID-19 test is currently marketed pursuant to EUAs we received from the FDA in June 2020, for point-of-care use, and in March 2021, for at-home and over-the-counter use without a prescription. If a test is not deemed waived, a manufacturer of a test categorized as moderate complexity may request categorization of the test as waived through a CLIA Waiver by Application submission to the FDA. The manufacturer must provide evidence to the FDA that a test meets the CLIA statutory criteria for waiver, including, among other things, that the test employs methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, which is issued by the Centers for Medicare & Medicaid Services, or CMS, the federal agency responsible for the oversight of clinical laboratories, which includes issuing waiver certificates. We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. If, for future tests, we fail to obtain, or experience significant delays in obtaining, a waiver approval by the FDA for our tests, our tests will only be able to be performed by CLIA certified or accredited and state licensed laboratories, which may limit our commercial success and have an adverse effect on our business, financial condition or operations. Further, if we fail to meet the requirements for our CLIA Waiver or California state laboratory license, we could be subject to significant fines, penalties, administrative sanctions, any of which could have an adverse effect on our business, financial condition or operations.

If we fail to comply with the FDA's QSR our manufacturing operations could be interrupted and our Cue Health Monitoring System sales and operating results could suffer.

Although full compliance may not be required under an EUA, we will be required to comply with some requirements of the FDA's QSR, which covers the methods used in, and the facilities and controls used for, the design, testing, manufacture, quality assurance, labeling, packaging, sterilization, storage and shipping of our tests. The FDA enforces the QSR through periodic announced and unannounced inspections of our manufacturing facilities. The failure by us or one of our current or future manufacturers or suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory authorities, or the failure to timely and adequately respond to any adverse inspectional observations, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, injunctions, civil penalties and criminal fines;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our tests;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for approval of a PMA or 510(k) clearance of new products, modified products or new indications of cleared products;
- withdrawing PMA approvals or reclassifying devices that have 510(k) clearances;
- refusal to grant export certificates for our tests; or
- criminal prosecution.

Any of these actions could impair our ability to produce our tests in a cost-effective and timely manner to meet our customers' demands once approved for marketing. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce components of our Cue Health Monitoring System on a timely basis and in the required quantities, if at all.

Our Cue Health Monitoring System is and will continue to be, subject to extensive regulation and compliance obligations, which are costly and time-consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required authorizations, clearances or approvals to commercialize our Cue Health Monitoring System and any current or future test.

The manufacture, labeling, advertising, promotion, record-keeping, post-market surveillance and marketing of medical devices are subject to extensive regulation and review by the FDA and numerous other governmental authorities in the United States as well as foreign countries where we may sell our tests. Even after we have obtained EUA approval, 510(k) clearance or PMA approval to market a product, we have ongoing responsibilities under FDA and other regulations. The FDA and other national governmental authorities have broad enforcement powers. The

regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs or lower than anticipated sales. Our failure to comply with applicable regulatory requirements could result in enforcement actions such as:

- civil penalties;
- delays on or denials of pending requests for 510(k) clearance or PMA approval;
- recalls or seizures;
- withdrawals or suspensions of current PMA approvals or reclassification of 510(k) cleared devices, resulting in prohibitions on sales of our tests, if approved;
- warning letters or untitled letters;
- operating restrictions, including a partial or total shutdown of production on our tests for any indication;
- refusal to issue export approvals or certifications;
- obtaining injunctions preventing us from manufacturing or distributing our products;
- commencing criminal prosecutions; and
- total prohibitions on our sales.

The incurrence or commencement of any such action would harm our reputation and cause sales of our tests to suffer and may prevent us from generating revenue.

In order to facilitate the rapid and thorough public health response to the COVID-19 pandemic, the CARES Act requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to report the results from each such test to the Secretary of U.S. HHS. The CARES Act also authorized the HHS Secretary to identify the form and manner, as well as the timing and frequency, of such reporting. Based on subsequent guidance issued by the U.S. HHS on June 4, 2020, all laboratories, including testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point-of-care or with at-home specimen collection related to SARS-CoV-2, will report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence. If governmental authorities conclude that our reporting processes do not comply with applicable law, we may be subject to penalties and other damages.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall

a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

The misuse or off-label use of our tests may harm our reputation or the image of our tests in the marketplace, or result in injuries that lead to product liability suits, which could be costly to our business. Moreover, we could be subject to FDA sanctions if we are deemed to have engaged in off-label promotion.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of a medical device for an indication that has not been approved or cleared by the FDA, referred to as an off-label use. The FDA does not restrict or regulate a physician's use of a medical device within the practice of medicine, and we cannot prevent a physician from using our tests for an off-label use. If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could subject us to regulatory or enforcement actions, including revocation of our existing EUA, additional civil money penalties, criminal fines and penalties, and exclusion from participation in federal health programs, among others. For example, in connection with our existing EUA, our COVID-19 test must comply with certain labeling requirements, including the label that our COVID-19 test has not been FDA cleared or approved but has been authorized by the FDA under an EUA and that our COVID-19 test has been authorized only for the detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens. Other federal, state or foreign governmental authorities might also take action if they consider our promotion or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and the use of our tests in the marketplace could be impaired.

Furthermore, the use of our tests for indications other than those that have been approved or cleared by the FDA may lead to performance issues or produce erroneous results, which could harm our reputation in the marketplace among physicians and consumers and increase the risk of product liability. Product liability claims are expensive to defend and could divert our management's attention from our primary business and result in substantial damage awards against us. Any of these events could harm our business, results of operations and financial condition.

Clinical trials necessary to support a future test submission will be expensive and may require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new tests and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a future EUA, 510(k), PMA, or de novo submission, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any test we advance into clinical trials may not have favorable results in later clinical trials.

We expect all of our tests in our expected future test menu to require clinical studies or trials.

Conducting successful clinical trials will require the enrollment of large numbers of subjects, and suitable subjects may be difficult to identify and recruit. Subject enrollment in clinical trials and completion of subject

participation depends on many factors, including the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the indication of the underlying test, the availability of appropriate clinical trial investigators, support staff, and proximity of subjects to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and subject compliance. In addition, subjects may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

In addition, our clinical trials may in the future be affected by the COVID-19 pandemic. For example, the COVID-19 pandemic may impact subject enrollment. In particular, some sites may pause enrollment to focus on, and direct resources to, COVID-19, while at other sites, subjects may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. As a result, potential subjects in our clinical trials may choose to not enroll, not participate in follow-up clinical visits, or drop out of the trial as a precaution against contracting COVID-19. Further, some subjects may not be able or willing to comply with clinical trial protocols if quarantines impede subject movement or interrupt healthcare services. We are unable to predict with confidence the duration of any such potential subject enrollment delays and difficulties, whether related to COVID-19 or otherwise. Delays in subject enrollment or failure of subjects to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our tests or result in the failure of the clinical trial.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of subjects than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate for approval. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner, or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product applications to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, including the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. On March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We expect to rely on third parties in conducting future clinical studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform such clinical studies satisfactorily.

We do not have the ability to independently conduct clinical studies that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as, laboratories, clinical investigators, CROs, consultants, and collaborators to conduct such studies if needed. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities but will not relieve us of our responsibilities. We will remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to current GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, or otherwise, we may be affected by increased costs, program delays or both, any resulting data may be unreliable or unusable for regulatory purposes, and we may be subject to enforcement action.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are subject to stringent and changing Data Protection Laws, Privacy Policies and Data Protection Obligations. The actual or perceived failure by us or our third-party service providers or vendors, to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

We are subject to numerous Data Protection Laws that govern the Processing of individually identifiable information and health information and Data Protection Obligations. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these Data Protection Laws could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

As we seek to expand our business, we are, and will increasingly become, subject to various Data Protection Laws as well as Data Protection Obligations, relating to the Processing of sensitive and personal information in the jurisdictions in which we operate. In many cases, these laws, regulations and standards apply not only to disclosures to third parties, but also to transfers of information between or among us and other parties with which we have commercial relationships. These Data Protection Laws may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. These laws and regulations include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, or collectively referred to as the HIPAA Rules, which establish a set of national privacy and security standards to safeguard Protected Health Information, or PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates and their subcontractors with whom such covered entities contract for services that involve the creation, receipt, maintenance or transmission of PHI for or on behalf of a covered entity or another business associate. HIPAA requires covered entities and business associates to, among other things, develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards

to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. As this applies to our business, we are required to maintain security standards for any PHI that we create, receive, maintain or transmit. For example, we plan to offer cloud-based portal software to help our customers more efficiently use our products. The software will maintain security safeguards that are designed to be consistent with the HIPAA Rules, but we cannot guarantee that these safeguards will not fail or that they will not be deemed inadequate in the future. In addition, we could be subject to periodic audits for compliance with the HIPAA Privacy and Security Standards by the U.S. HHS, and our customers. The U.S. HHS Office for Civil Rights may impose significant penalties on entities subject to HIPAA for a failure to comply with a requirement of the HIPAA Rules. Penalties will vary significantly depending on factors such as the date of the violation, whether the entity knew or should have known of the failure to comply, or whether the entity's failure to comply was due to willful neglect. A single breach incident may violate multiple standards. In addition, a person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face significant criminal penalties and imprisonment. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Additionally, if we are unable to properly protect the privacy and security of the PHI of our customers, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information, including health-related information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Confidentiality of Medical Information Act, or CMIA, which is a state version of the HIPAA Rules, that protects "medical information" held by providers of health care, health plans, and subcontractors, specifically regulates mobile applications used for, among other things, the diagnosis of medical conditions as "health care providers pursuant to Section 56.06 of the Civil Code. This means that we are subject to additional privacy requirements that are not otherwise applicable to business associates under the HIPAA Rules. If, for example, we were to disclose information to a third party where such disclosure is not permitted by CMIA, we could be subject to administrative fines and/or civil penalties per violation that vary based on whether the disclosure was due to negligence, was done knowingly and willfully, or was knowingly and willfully and "for purposes of financial gain," The CMIA also imposes criminal penalties. Section 56.36 provides that any violation of the CMIA's nondisclosure provisions that results in an economic loss or personal injury to a patient is punishable as a misdemeanor. Moreover, unlike HIPAA, CMIA authorizes a private right of action for any violation of its provisions, including inappropriate access to, use, or disclosure of "medical information." Actual injuries are not required to bring an action under CMIA. The courts may award nominal damages of $1,000 per person, plus costs and attorney's fees for a negligent disclosure and may award compensatory and punitive damages, plus attorneys costs and attorneys fees for economic losses or personal injury resulting from the disclosure. This private right of action may increase the likelihood of, and risks associated with, litigation in association with any data breach.

Another recent California law, the California Consumer Privacy Act of 2018, or CCPA, increases privacy rights for California residents and imposes stringent data privacy and security obligations on companies that process their personal information, came into effect on January 1, 2020. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information but does not apply to health care providers subject to CMIA or business associates subject to HIPAA. In addition, laws governing online privacy, such as the California Online Privacy Protection Act, or CalOPPA, applies to our mobile application and online services. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended from time to time, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. Further, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, that goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their sensitive information, provide for penalties for CPRA violations concerning California residents

under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the law. As the number and breadth of California privacy law increases, it is possible that we may be subject to additional standards or enforcement authorities under laws such as CCPA or CPRA in the future with respect to some of the information that we collect or maintain.

Although California often leads the nation in privacy laws, state laws are also changing rapidly. Additional states are enacting more stringent consumer privacy laws, and there is continuing discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Laws, regulations and standards in many other jurisdictions also apply broadly to the Processing of personal information, which impose significant compliance obligations. For example, in the European Economic Area, or EEA, and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR, which came into effect in May 2018. The GDPR imposes stringent data privacy and security requirements on companies in relation to the processing of personal data of data subjects within the EEA and the United Kingdom. The GDPR, together with national legislation, regulations and guidelines of the EEA member states and the United Kingdom governing the Processing of personal data, impose strict obligations and restrictions on the ability to Process personal data, including health data from clinical trials and adverse event reporting. The law is also developing rapidly and, in July 2020, in its Schrems II ruling, the Court of Justice of the EU invalidated the EU-U.S. Privacy Shield data transfer mechanism, limiting how organizations could lawfully transfer personal data from the EEA to the U.S. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts (including being called into question in Schrems II), may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. In addition, the European Commission recently proposed updates to the Standard Contractual Clauses. Such developments may cause us to have to make further expenditures on local infrastructure, limit our ability to Process personal data, change internal business processes or otherwise affect or restrict sales and operations. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any Data Protection Laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential information, whether by us, one of our service providers or another third party, could negatively affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit for a period of time, Brexit has created uncertainty with regard to the future regulation of data and data protection in the United Kingdom. Other countries also are considering or have passed legislation requiring local storage, processing or security of data, or similar requirements, which could increase the cost and complexity of delivering our products.

We will make public statements about our use and disclosure of personal information through our Cue Virtual Care Delivery Apps and external Privacy Policies. Although we endeavor to comply with our external Privacy Policies, we may at times fail to do so or be alleged to have failed to do so. The publication of our external Privacy Policies that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our external Privacy Policies, Data Protection Laws, or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products or processes compromise the privacy of

customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose unencrypted personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected customers, regulators, credit reporting agencies or other affected individuals of a security breach. Such notifications are costly, and the disclosures or the failure to comply with such requirements, could lead to material adverse effects, including without limitation, negative publicity, a loss of customer confidence in our services or security measures or breach of contract claims. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with applicable Data Protection Laws, Data Protection Obligations or other legal obligations. In addition, although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach by our subcontractors could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and Data Protection Laws and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business.

We cannot assure you that our third-party partners and service providers with access to our or our customers', suppliers' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us or violate Data Protection Laws, or that they will not experience security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under the Data Protection Laws, which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy- and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

We may receive inquiries or be subject to investigations, proceedings or actions, by various government entities regarding our privacy and information security practices and Processing ("Regulatory Proceedings"). These Regulatory Proceedings could result in a material adverse effect, including without limitation, interruptions of, or required changes to, our business practices, the diversion resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary Processing, or other remedies that adversely affect our business.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations,

standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

While we maintain general liability insurance coverage, cyber insurance coverage and other insurance, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our privacy and security practices, Processing or security breaches we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Laws and regulations affecting government contracts and grants, including our grants, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws, regulations, and agency-specific policies and procedures relating to the administration and performance of our grant and sub-award agreements. Among the most significant are:

- the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the AKS, the Procurement Integrity Act, the FCA and the FCPA; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices, including unique accounting requirements regarding allowable and unallowable costs, and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenue reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event the U.S. government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, it would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies. In addition, the qui tam provisions of the civil FCA authorize a private person to file civil actions on behalf of the federal and state governments and retain a share of any recovery, which can include treble damages and civil penalties.

If we or our suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations, and the manufacturer of our products, involve the production and use of hazardous and flammable materials and waste, including chemicals and biological materials. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting

damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

We are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims, we could face substantial penalties and our business operations and financial condition could be harmed.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with healthcare professionals and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We intend to have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. There are similar laws in other countries. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws.

The laws that may affect our ability to operate include, among others:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of a person, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities. Certain common business activities including, certain reimbursement support programs, educational and research grants or charitable donations, and practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such people as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within any available exception or safe harbor and would be subject to a facts and circumstances

analysis to determine compliance with the Anti-Kickback Statute. Our business may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability;

- The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, which prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute);
- the federal false claims and civil monetary penalties laws, including the Civil Monetary Penalties Law and the FCA, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Actions under the FCA may be brought by the government or as a qui tam action by a private person in the name of the government. These people, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any monetary recovery. Many medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the FCA for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Medical device manufacturers and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates and their subcontractors that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- various state laws govern the privacy and security of personal information, including the CMIA, which provides for a private right of action for data breaches;
- the federal Physician Payments Sunshine Act, implemented as Open Payments, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be

required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or the BBA, increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, FCA and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices of our Cue Health Monitoring System, and financial arrangements with physicians, other healthcare providers, and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti-Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil FCA and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling FCA, Anti-Kickback Statute or civil monetary penalties law cases also may enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, or the OIG, in order to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the OIG, the U.S. Department of Justice, or the DOJ, the state attorney generals and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorney generals and other government agencies, could harm our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators, (2) manufacturing standards, (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We intend to adopt a code of business conduct and ethics prior to the completion of this offering that applies to our directors, officers and employees, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

Healthcare policy changes may have a material adverse effect on our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, enacted in March 2010, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which the ACA may significantly impact our business, the ACA includes: provisions regarding coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures; initiatives to revise Medicare payment methodologies; and initiatives to promote quality indicators in payment methodologies.

Since enactment of the ACA, there have been, and continue to be, numerous executive and legal challenges and Congressional actions to repeal and replace provisions of the law. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and the medical device tax and, effective January 1, 2021, also eliminated the health insurer tax.

During his term, President Trump signed several Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 28, 2021, however, President Biden issued a new Executive Order which directed federal agencies to reconsider rules and other policies that limit Americans’ access to health care and consider actions to protect and strengthen that access. Under this Executive Order, federal agencies were directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health

insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On June 17, 2021, the Supreme Court held that the states and individuals that brought the lawsuit challenging the ACA's individual mandate do not have standing to challenge the law. The Supreme Court did not reach the merits of the challenge, but the decision ends the case. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden Administration will impact the ACA.

In addition, there have been numerous governmental reform activities in response to the COVID-19 pandemic. For example, the FFCRA authorized state Medicaid programs to provide access to coverage for certain medically necessary testing, testing-related services and treatment related to COVID-19 at no cost to the individual during the emergency period. Such programs are evolving and vary among state Medicaid programs. In addition, the California Department of Health Care Services implemented a COVID-19 Uninsured Group program on August 28, 2020. Under the program, California covers COVID-19 diagnostic testing, testing-related services, and treatment services, including hospitalization and all medically necessary care, at no cost to the individual, for up to 12 months or the end of the public health emergency, whichever comes first. It is possible that additional governmental action will be taken to address the COVID-19 pandemic, which may impact our business.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government's role in the U.S. healthcare industry as a result of the ACA's implementation, and changes to the reimbursement amounts paid by Medicare and other payors for our tests and our planned future tests, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows.

We cannot predict the impact changes to these laws or the implementation of, or changes to, any other laws applicable to us in the future may have on our business, financial condition and results of operations.

Risks Related to Our Common Stock and the Offering

There has been no prior public market for our common stock and an active trading market for our common stock may never develop or be sustained.

No public market for our common stock currently exists. An active public trading market for our common stock may not develop following the completion of this offering, or if developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration. The initial public offering price of shares of our common stock has been determined by negotiation between us and the underwriters and may not be indicative of prices that will prevail following the completion of this offering. The market price of shares of our common stock may decline below the initial public offering price, and you may not be able to resell your shares of our common stock at or above the initial public offering price.

Our stock price may be volatile, and the value of our common stock may decline.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including, but not limited to:

- actual or anticipated fluctuations in our financial condition or results of operations;
- variance in our financial performance from expectations of securities analysts;
- changes in the pricing of our products;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our products;

- changes in the number of enterprise customers we are able to partner with;
- the level of market adoption of the Cue Health Monitoring System, including in the over-the-counter and at-home context;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- changes in the structure of healthcare payment systems;
- significant data breaches of our company, providers, vendors or pharmacies;
- our involvement in litigation;
- future sales of our common stock by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- negative publicity, such as whistleblower complaints or unsupported allegations made by short sellers, about us or our products;
- the trading volume of our common stock;
- changes in investor perceptions of us or our industry;
- changes in the anticipated future size and growth rate of our market;
- the effect of the COVID-19 pandemic and the end of the COVID-19 pandemic on our business;
- general economic, political, regulatory, industry, and market conditions; and
- natural disasters or major catastrophic events.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In recent years, stock markets in general, and the market for life science technology companies in particular (including companies in the genomics, biotechnology, diagnostics and related sectors), have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Future sales of our common stock in the public market could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market following the completion of this offering, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

All of our directors and officers and the holders of substantially all of our capital stock and securities convertible into our capital stock are subject to lock-up agreements that restrict their ability to transfer shares of our capital stock for 180 days from the date of this prospectus. These lock-up agreements limit the number of shares of capital stock that may be sold immediately following this offering, subject to certain exceptions. Subject to certain limitations, substantially all of these shares will become eligible for sale upon expiration of the 180-day lock-up period. Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC may, in their sole discretion, permit our stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. For additional information, see the section titled "Underwriting."

In addition, there were 9,944,197 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2021. We intend to register all of the shares of common stock issuable upon exercise of such outstanding options or other equity incentives we may grant in the future, for public resale under the Securities Act of 1933, as

amended, or Securities Act. The shares of common stock will become eligible for sale in the public market to the extent such options are exercised, subject to the lock-up agreements described above and compliance with applicable securities laws.

Beginning 180 days after this offering, holders of approximately 111,434,865 shares of our common stock, including 18,611,914 shares of our common stock that will have been issued pursuant to the conversion of the Convertible Notes upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

The issuance of shares in connection with any subsequent issuance could depress the market price of our common stock. We are unable to predict the effect that such issuances and/or sales may have on the prevailing market price of our common stock.

If you purchase shares of our common stock in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity or equity-linked securities in the future.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock immediately after this offering. If you purchase shares of our common stock in this offering, you will suffer immediate dilution of $12.17 per share, representing the difference between our pro forma as adjusted net tangible book value per share as of June 30, 2021, after giving effect to the sale of shares of common stock in this offering and the initial public offering price of $16.00 per share. See the section titled “Dilution.”

If we issue additional shares of common stock, or securities convertible into or exchangeable or exercisable for shares of common stock, our stockholders, including investors who purchase shares of common stock in this offering, will experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, as amended, or JOBS Act. For so long as we remain an emerging growth company, we are permitted by the U.S. Securities and Exchange Commission, or SEC, rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies.

These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes–Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different from the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions.

In addition, as an emerging growth company the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have elected to use this extended transition period under the JOBS Act; however, we may choose to early adopt new or revised accounting pronouncements, if permitted under such pronouncements.

If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We do not expect to pay any dividends for the foreseeable future. Investors in this offering may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We have never declared or paid cash dividends on our capital stock, and we do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain all available funds and future earnings to fund the development and expansion of our business. In addition, any credit facility or other financing we obtain may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds to us from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, our ultimate use may vary substantially from our currently intended use. Investors will need to rely upon the judgment of our management with respect to the use of proceeds. Pending use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper, and guaranteed obligations of the United States government that may not generate a high yield for our stockholders. If we do not use the net proceeds that we receive in this offering effectively, our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline.

Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based on the number of shares of common stock outstanding as of June 30, 2021 and including the 12,500,000 shares to be sold in this offering, 83,526,065 shares of common stock issuable upon the automatic conversion of our redeemable convertible preferred stock outstanding as of June 30, 2021 into an equal number of shares of our common stock immediately prior to the completion of this offering and the automatic conversion of our outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own approximately 41.2% of our common stock (assuming no exercise of the underwriters' option to purchase up to 1,875,000 additional shares of our common stock and no purchases of shares in this offering or in the directed share program). These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

Some of these persons or entities may have interests different than those of investors purchasing shares in this offering. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. The foregoing discussion does not reflect any potential purchases by our existing principal stockholders or their affiliated entities of shares of our common stock in this offering.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect at the completion of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the completion of this offering, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our

stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

For information regarding these and other provisions, see the section titled "Description of Capital Stock."

General Risk Factors

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, which we expect to further increase after we are no longer an emerging growth company. The Sarbanes–Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market LLC and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will devote a substantial amount of time to compliance with

these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the specific timing of such costs.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We will be required, pursuant to Section 404 of the Sarbanes–Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2022, which is the year covered by the second annual report following the completion of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time. We are commencing the costly and challenging process of compiling the information systems, processes and internal controls documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act, but we may not be able to complete our evaluation, testing and any required remediation in a timely fashion once initiated. Our compliance with Section 404 of the Sarbanes–Oxley Act will require that we incur substantial accounting expenses and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes–Oxley Act.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

For a discussion of material weaknesses that were identified in connection with the audit of our 2019 and 2020 financial statements see "—We have identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, as a result of which, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock" above.

Our amended and restated certificate of incorporation that we intend to adopt effective immediately prior to the completion of this offering will designate the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our amended and restated certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum

provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Accordingly, the exclusive forum provision does not designate the Court of Chancery as the exclusive forum for any derivative action arising under the Exchange Act, as there is exclusive federal jurisdiction in that instance, and instead designates the federal district court for the District of Delaware for such an action.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the enforceability of our exclusive forum provision is uncertain, and a court may determine that such provision will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction. Further, compliance with the federal securities laws and the rules and regulations thereunder cannot be waived by investors in our common stock.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could significantly harm our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard if and when we have product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our common stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our expectations regarding our revenue, expenses and other operating results;
- the extent and duration of the COVID-19 pandemic and the impact of the end of the COVID-19 pandemic on our business and our expectations regarding customer and user demand for our COVID-19 test;
- our ability to increase demand for, and the rate of market adoption of, the Cue Health Monitoring System and our platform, tests and other products generally, including with consumers, healthcare professionals, enterprises, insurers and other payors and public health officials;
- our ability to effectively scale our manufacturing capacity and other operations in a timely manner in order to meet contractual obligations, market demand and to be able to successfully operate our business;
- our ability to meet our contractual obligations under our agreement with the U.S. Department of Defense or other customers;
- our ability to successfully develop and commercialize additional tests and other products for use with our Cue Integrated Care Platform;
- our expectations of the reliability, accuracy and performance of our products and services, as well as expectations of the benefits to patients, clinicians and providers of our products and services;
- our ability to obtain and maintain regulatory authorizations, clearances or approvals for our tests, including our existing FDA EUAs for our COVID-19 test;
- our ability to accurately forecast demand for the Cue Health Monitoring System, our tests and other products;
- our ability to successfully build out our sales and marketing infrastructure, the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payors and expand geographically;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- the performance of our third-party suppliers and our ability to avoid any disruption in sources of supply;
- our ability to effectively manage our growth, including our ability to retain and recruit personnel, and maintain our culture;
- the impact of U.S. and international laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing products and services;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements, future revenue, expenses, the ability to obtain reimbursement for our products and any needs for additional financing;
- our expectations regarding technology trends and developments in the healthcare industry and our ability to address those trends and developments with our offerings;

- our expectations concerning relationships with third parties, including healthcare professionals, enterprises, insurance companies and other payors, public health officials and other stakeholders in the healthcare system;
- the degree to which we are able to help bring about a new healthcare paradigm, and be a significant participant in any such new paradigm;
- our ability to grow our business internationally, in addition to within the United States;
- our ability to implement, maintain and improve effective internal controls and remediate material weaknesses;
- our expectations related to the use of proceeds from this offering and the sufficiency of such proceeds, together with our existing cash and cash equivalents, to fund our operations; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

MARKET, INDUSTRY AND OTHER DATA

This prospectus includes statistical and other industry and market data that we obtained from independent industry publications and research, surveys and studies conducted by independent third parties as well as our own estimates of potential market opportunities. Certain of these publications, surveys and studies were published before the COVID-19 pandemic and therefore do not reflect any impact of COVID-19 on any specific market. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our products include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $179.2 million, or approximately $207.1 million if the underwriters exercise their option to purchase additional shares in full, based on the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of June 30, 2021, we had cash and cash equivalents of $246.3 million (excluding restricted cash of $6.0 million as of such date). We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $60.0 million to $70.0 million for the continued commercial scale up of our activities and build out our corporate infrastructure, other than the scale up of manufacturing facilities and capabilities, including the hiring and training of sales and marketing personnel and to fund marketing initiatives and for the hiring and training of other personnel;
- approximately $30.0 million to $35.0 million for the continued scale up of our manufacturing facilities and capabilities;
- approximately $60.0 million to $65.0 million for research and development to continue to develop each of our planned tests in our near-term development pipeline, which includes:
    - approximately $40.0 million to $45.0 million for further development and clinical studies for each of our five tests in late-stage technical development (flu, RSV, pregnancy, fertility, and inflammation); and
    - approximately $20.0 million to further develop our software and other technical capabilities, such as the development of the Cue Data & Innovation Layer and the Cue Ecosystem Integrations and Apps; and
- the remainder, if any, for working capital and other general corporate purposes.

We may use a portion of the net proceeds for acquisitions or strategic investments in complementary businesses, services, products or technologies. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time.

Based on our current plans, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to meet our working capital and capital expenditure needs and debt service obligations for at least the next 12 months. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, cash anticipated to be generated by ongoing operations, and will be sufficient to fund development of our currently contemplated near-term development pipeline, through completion of product development and regulatory authorization, clearance or approval, as applicable, although we cannot assure you that this will be the case. While we expect that the costs associated with getting any one of our tests authorized, cleared or approved by the FDA will vary, and we are unable to predict with specificity the cost that will be required to complete any particular test, we expect that each planned test in our near-term development pipeline, including our five tests in late-stage technical development, will cost on average between approximately $10.0 million to $20.0 million in order to complete development and obtain regulatory authorization, clearance or approval, as applicable.

This expected use of net proceeds from this offering and our existing cash and cash equivalents represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including cash flows from operations and the anticipated growth of our business. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our results of operations, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, any future credit facility or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect immediately prior to the completion of this offering, (ii) the automatic conversion of all of our outstanding $235.5 million aggregate principal amount Convertible Notes into 18,611,914 shares of common stock upon the completion of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, (iii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock immediately prior to the completion of this offering, and (iv) the automatic conversion of all of our outstanding warrants to purchase redeemable convertible preferred stock into warrants to purchase common stock, and the related reclassification of our redeemable convertible preferred stock warrant liabilities to additional paid-in capital immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect: (i) the pro forma adjustments set forth above, and (ii) the issuance and sale of 12,500,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our financial statements and the related notes included elsewhere in this prospectus and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this prospectus.

(in thousands, except share and per share data)	As of June 30, 2021		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted
Cash and cash equivalents	$246,326	$ 246,326	$ 425,526
Restricted cash, non-current	6,000	6,000	6,000
Redeemable convertible preferred stock warrant liabilities	$ 1,521	$ —	$ —
Convertible notes	258,734	—	—
Accrued interest on convertible notes	1,026	—	—
Finance leases, including current portion	3,043	3,043	3,043
Series A redeemable convertible preferred stock, $0.00001 par value per share; 8,721,437 shares authorized, 8,350,743 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	7,519	—	—
Series B redeemable convertible preferred stock, $0.00001 par value per share; 46,213,620 shares authorized, 46,176,715 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	66,186	—	—
Series C-1 redeemable convertible preferred stock, $0.00001 par value per share; 27,308,229 shares authorized, 27,308,227 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	96,436	—	—
Series C-2 redeemable convertible preferred stock, $0.00001 par value per share; 1,690,380 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	6,182	—	—
Stockholders' equity (deficit):			
Common stock, $0.00001 par value: 129,030,355 shares authorized 29,128,604 shares issued and outstanding, actual; 500,000,000 shares authorized, 131,266,583 shares issued and outstanding, pro forma; 500,000,000 shares authorized, 143,766,583 shares issued and outstanding, pro forma as adjusted	—	—	—
Preferred stock, $0.00001 par value: no shares authorized, issued or outstanding, actual; 50,000,000 shares authorized, no shares issued and outstanding, pro forma; 50,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	—	—	—
Additional paid-in capital	16,264	506,784	685,984
Accumulated deficit	(77,596)	(130,494)	(130,494)
Total stockholders' (deficit) equity	(61,332)	376,290	555,490
Total capitalization	$379,315	$ 379,333	$ 558,533

The number of shares of our common stock issued and outstanding and pro forma and pro forma as adjusted in the table above is based on 131,266,583 shares of our common stock outstanding as of June 30, 2021, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of common stock immediately prior to the completion of this and the automatic conversion of outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, but excludes:

- 9,944,197 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2021, with a weighted-average exercise price of $4.93 per share;
- 1,049,043 shares of common stock subject to restricted stock units, or RSUs, outstanding as of June 30, 2021;
- 75,744 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2021 to purchase shares of common stock, with an exercise price of $0.40 per share;

- 79,882 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2021 to purchase redeemable convertible preferred stock that will automatically become warrants to purchase 79,882 shares of common stock immediately prior to the completion of this offering, with a weighted-average exercise price of $1.12 per share;
- 1,138,635 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, as of June 30, 2021, of which our board of directors granted stock awards covering 128,000 shares of common stock to certain of our non-employee directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part;
- 14,173,771 additional shares of common stock that are available for future issuance under our 2021 Stock Incentive Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Stock Incentive Plan, of which our board of directors granted awards covering 9,763,966 shares of common stock to certain of our employees and executive officers and an additional 56,250 shares of common stock, based on the initial public offering price of $16.00 to certain of our non-employee directors, in each case, effective immediately prior to the commencement of trading of our common stock on the Nasdaq Stock Market; and
- 2,834,754 additional shares of common stock that are available for future issuance under our 2021 Employee Stock Purchase Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Employee Stock Purchase Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of June 30, 2021 was $(68.0) million, or $(2.33) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets (total assets less intangible assets and deferred offering costs) less our total liabilities and the carrying value of our redeemable convertible preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 29,128,604 shares of common stock outstanding as of June 30, 2021.

Our pro forma net tangible book value as of June 30, 2021 was $368.1 million, or $2.80 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the filing and effectiveness of our amended and restated certificate of incorporation, which will be in effect upon completion of this offering, (ii) the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock upon the completion of this offering and the automatic conversion of our outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, upon the completion of this offering, and (iii) the automatic conversion of all of our outstanding warrants to purchase redeemable convertible preferred stock into warrants to purchase common stock, and the related reclassification of our redeemable convertible preferred stock warrant liability to additional paid-in capital immediately prior to the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of June 30, 2021, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 12,500,000 shares of our common stock in this offering at the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2021 would have been $551.2 million, or $3.83 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $1.03 to existing stockholders and immediate dilution of $12.17 in pro forma as adjusted net tangible book value per share to new investors purchasing shares of common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$16.00
Historical net tangible book value (deficit) per share as of June 30, 2021	$(2.33)	
Increase in net tangible book value per share attributable to the pro forma adjustments described above	5.14	
Pro forma net tangible book value per share as of June 30, 2021, before giving effect to this offering	2.80	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	1.03	
Pro forma as adjusted net tangible book value per share after this offering		3.83
Dilution in pro forma as adjusted net tangible book value per share to new investors participating in this offering		$12.17

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $3.98, representing an immediate increase in pro forma as adjusted net tangible book value per share of $0.14 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of $12.02 to new investors purchasing shares of common stock in this offering, based on the initial public offering price of $16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of June 30, 2021, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at the initial public offering price of $16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares of common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders(1)	131,266,583	91%	$427,600,000	68%	$ 3.26
New investors	12,500,000	9	200,000,000	32	$16.00
Total	143,766,583	100%	$627,600,000	100%	

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise purchase in this offering.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise their option to purchase additional shares in full, the number of shares of our common stock held by existing stockholders would be reduced to 90% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing shares of common stock in this offering would remain at 9% of the total number of shares of our common stock outstanding after this offering.

The foregoing tables and calculations (other than historical net tangible book value) are based on 131,266,583 shares of our common stock outstanding as of June 30, 2021, after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of common stock immediately prior to the completion of this offering and the automatic conversion of our outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock upon the closing of this offering, based on accrued interest through Septemeber 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share), but excludes:

- 9,944,197 shares of common stock issuable upon exercise of stock options outstanding as of June 30, 2021, with a weighted average exercise price of $4.93 per share;
- 1,049,043 shares of common stock subject to restricted stock units, or RSUs, outstanding as of June 30, 2021;
- 75,744 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2021 to purchase shares of common stock, with an exercise price of $0.40 per share;
- 79,882 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2021 to purchase redeemable convertible preferred stock that will automatically become warrants to purchase 79,882 shares of common stock immediately prior to the completion of this offering, with a weighted-average exercise price of $1.12 per share;
- 1,138,635 shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan, as of June 30, 2021, of which our board of directors granted stock awards covering 128,000 shares of common stock to certain of our non-employee directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part;
- 14,173,771 additional shares of our common stock that are available for future issuance under our 2021 Stock Incentive Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Stock Incentive Plan, of which our board of directors granted awards covering 9,763,966 shares of common stock to certain of our employees and executive officers and an additional 56,250 shares of common stock, based on the initial public offering price of $16.00 to certain of our non-employee directors, in each case, effective immediately prior to the commencement of trading of our common stock on the Nasdaq Stock Market; and
- 2,834,754 additional shares of our common stock that are available for future issuance under our 2021 Employee Stock Purchase Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Employee Stock Purchase Plan.

To the extent stock options are issued and exercised or new awards are granted under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors purchasing shares of common stock in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the financial condition and results of operations should be read together with our financial statements and the related notes thereto included elsewhere in this prospectus. The discussion and analysis should also be read together with the section titled "Business." The following discussion contains forward-looking statements that reflect future plans, estimates, beliefs and expected performance. The forward-looking statements are dependent upon events, risks and uncertainties that may be outside of our control. Our actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in the sections titled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements."

Overview

We are a health technology company, and our mission is to enable personalized, proactive and informed healthcare that empowers people to live their healthiest lives. Our proprietary platform, the Cue Integrated Care Platform, which is comprised of our Cue Health Monitoring System, Cue Data and Innovation Layer, Cue Virtual Care Delivery Apps, and Cue Ecosystem Integrations and Apps, enables lab-quality diagnostics-led care at home, at work or at the point of care. Our platform is designed to empower stakeholders across the healthcare ecosystem, including consumers, providers, enterprises and payors with paradigm-shifting access to diagnostic and health data to inform care decisions. We are helping pioneer a new continuous care model that we believe has the potential to significantly improve the user experience, provide measurable and actionable clinical insights, and increase efficiency within the healthcare ecosystem. We believe this model, powered by our platform, will allow users to actively manage their health, which we believe will lead to improved health outcomes and a more resilient, connected, and efficient healthcare ecosystem for all stakeholders.

The Cue Integrated Care Platform consists of the following hardware and software components: (1) our revolutionary Cue Health Monitoring System, made up of a portable, durable and reusable reader, or Cue Reader, a single-use test cartridge, or Cue Cartridge, and a sample collection wand, or Cue Wand, (2) our Cue Data and Innovation Layer, with cloud-based data and analytics capability, (3) our Cue Virtual Care Delivery Apps, including our consumer-friendly Cue Health App and our Cue Enterprise Dashboard, and (4) our Cue Ecosystem Integrations and Apps, which allow for integrations with third party applications and sensors.

Our Cue Health Monitoring System is designed to deliver a broad menu of tests through one system, enabling two major testing modalities, nucleic acid amplification tests, or NAAT, and immunoassays, in one device. Our system is designed to handle different sample types, including saliva, blood, urine and swabs, and can detect nucleic acids, small molecules, proteins and cells. We believe this will enable us to address many of the diagnostic tests conducted in clinical laboratories, such as tests addressing indications in respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management.

We designed our platform with the consumer in mind. Our platform, although underpinned by breakthrough technology, is simple to operate and is comprised of the following elements:

- *Cue Health Monitoring System*
  - *Cue Reader*: The Cue Reader is an elegantly designed, automated analyzer of test results and is used with Cue Test Kits and the Cue Health App. The Cue Reader runs the Cue Cartridge and communicates the result of the test digitally via Bluetooth to the Cue Health App.
  - *Cue Test Kit*: Each Cue Test Kit is comprised of a Cue Cartridge and a Cue Wand.
    - *Cue Cartridge*: Our sample-specific, single-use cartridges are designed to handle different chemistries, which allows us to create a broad menu of tests. Cue Cartridges are designed to be seamlessly inserted into the Cue Reader.
    - *Cue Wand*: Cue Wands are single-use and sterile sample collection devices that are designed to be universally compatible with the Cue Cartridges. The Cue Wand is designed to permit collection of multiple sample types, including saliva, blood, urine and swabs, with only minor modifications.

Our cloud-native Cue Data and Innovation Layer stores and curates the data from our Cue Health Monitoring System and provides a secure environment for users to access current and historical health data. Our Data and Innovation Layer has the ability to collate unstructured and structured data from a wide variety of data sources, which we believe will give us the ability in the future to store and analyze more holistic sets of health data, including from other testing modalities and wearables. The Cue Integrated Care Platform was built with data security and regulatory compliance, including HIPAA, at its core.

The Cue Data and Innovation Layer provides the foundation for our Cue Virtual Care Delivery Apps and has enabled the development of our Cue Ecosystem Integrations and Apps. The Cue Data and Innovation Layer currently contains an API that allows for the data from tests performed on the Cue Health Monitoring System to be received, stored, and retrieved by the end user. For enterprises deploying the Cue Enterprise Dashboard, the Cue Data and Innovation Layer enables the creation of a network of users affiliated by roles with the enterprise. Within this network of users, the Cue Data and Innovation Layer provides the engine behind test analytics, creation of groups, scheduling and compliance, reporting, and enterprise-specific privacy policy management. The Cue Data and Innovation Layer powers the EMR integration with major EMR providers.

- *Cue Virtual Care Delivery Apps*
  - *Cue Health App*: Our mobile app creates a secure interface between the user and their health data. For consumers, it allows a single point of entry for their health data; for healthcare professionals, it is designed to provide a unified platform for managing patient histories and, in the future, is expected to allow for telemedicine and e-prescription services. By connecting the diagnostic test results with interventions and outcomes, we believe the Cue Health App will allow users to be more engaged and satisfied with their healthcare experience, which can ultimately drive better outcomes for users. To run a Test Kit on the Cue Reader, a user will need to download and utilize the Cue Health App. As of August 31, 2021, through our 49 active customers, over 45,000 unique accounts have used the Cue Health App to run our COVID-19 Test Kit. These unique accounts include both organizations and individuals who may take tests episodically, healthcare providers running a large number of tests for multiple patients, and enterprises running a large number of tests for their entire organization, as established by the customer on a customer-by-customer basis.
  - *Cue Enterprise Dashboard*: Our dashboard is designed to allow enterprises, payors, healthcare providers and public health entities to manage population health at the organizational level and has the potential to track the efficacy of various population health programs. Accessible online, the Cue Enterprise Dashboard has the potential to help organizations manage a patient's journey from onboarding to scheduling, care management and inventory management. The Cue Enterprise Dashboard was built with a focus on user experience, simplifying the sharing of communications, such as results, records, and histories with patients and across providers and streamlining reporting requirements. Powered by our analytics engine and role-based access capabilities, it is designed to provide chief medical officers, environmental health and safety officials, and benefits managers with insight into their organization's population health, helping to facilitate efficient decision making. As of August 31, 2021, we had approximately 60 active public sector, enterprise and provider accounts on the Cue Enterprise Dashboard. An account on the Cue Enterprise Dashboard is considered active if the customer has signed into their account and utilized the programs within the last six months. A customer may have more than one active account on the Cue Enterprise Dashboard.
- *Cue Ecosystem Integrations and Apps*: We believe that placing our APIs at the core of our integrated care platform will enable us to become foundational within Healthcare 2.0. Our Cue Data and Innovation Layer is designed to be able to securely connect with on-demand services, such as telemedicine, and e-prescription services, which we believe we will enable a truly digital and seamless user experience. In the future, we plan on enhancing our platform to enable third party application development and offerings that complement our solutions.

In addition, our ability to integrate with anchor EMR systems, such as Epic Systems Corporation, or Epic, allows our customers to integrate our platform with their existing systems, creating an agile and responsive workflow for patient monitoring for ongoing care, better intelligence and reporting, and more efficient provider level health management.

These components of the Cue Integrated Care Platform are designed to work together seamlessly, creating an easy-to-use workflow for our consumers.

Our first, and currently only, commercially available diagnostic test for our Cue Health Monitoring System is our COVID-19 test for ribonucleic acid, or RNA, of SARS-CoV-2, the virus that causes COVID-19. In June 2020, the U.S. Food & Drug Administration, or the FDA, granted an Emergency Use Authorization, or EUA, for our molecular COVID-19 test for use under the supervision of qualified medical personnel. In March 2021, the FDA granted us an EUA for over the counter and at-home use of our COVID-19 test without a prescription. Internationally, we have also received the CE mark in the European Union, as well as Interim Order authorization from Health Canada, which is the department of the Government of Canada responsible for national health policy. In June 2021, our COVID-19 test also received regulatory approval from the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India. Our COVID-19 test is authorized for use by both symptomatic and asymptomatic individuals, and by adults and children aged two and older with adult assistance.

We have experienced substantial growth since the commercial launch of our COVID-19 test in June 2020. As of August 31, 2021, we have delivered over 115,000 Cue Readers and over five million Cue Cartridges across the United States, which have been deployed to over 250 school districts, nursing homes, hospitals, public health facilities and organizations, essential businesses, correctional facilities, other public sector users, enterprise customers and healthcare providers, and secured commercial agreements with the U.S. Department of Defense, enterprise customers, and healthcare providers, as of August 15, 2021. We intend to continue to broaden our product offerings, as well as enhance and further develop our integration into connected healthcare.

Prior to August 2020, we were focused on research and development of our platform and did not generate any revenue from product sales. We began generating revenue from product sales in August 2020 following the receipt of our first EUA from the FDA for our COVID-19 test in June 2020. Of our approximately $23.0 million in revenue in the year ended December 31, 2020, approximately $15.4 million was from product sales. Of that amount, $8.9 million of product revenue was from public sector entities, substantially all of which was from the U.S. DoD, and the remaining $6.5 million of product revenue was generated from other customers. All of our approximately $201.9 million in revenue in the six months ended June 30, 2021 was from product sales. Of that amount, $167.1 million of product revenue was from public sector entities, substantially all of which was from the U.S. DoD, and the remaining $34.8 million of product revenue was primarily generated from sales to a single non-government enterprise customer (which accounted for $28.9 million of revenue during the six months ended June 30, 2021) and other non-public sector customers. After the conclusion of the initial U.S. DoD agreement, we anticipate that the percentage of our revenue derived from non-public sector customers will increase as we continue to ramp up our manufacturing and distribution capabilities and are able to sell more of our products to other customers, including enterprises and healthcare providers. Our net loss was $47.4 million for the year ended December 31, 2020, and our net income was $32.8 million for the six months ended June 30, 2021.

Currently, the majority of our product revenue comes from the sale of Cue Test Kits with a smaller proportion coming from the sale of Cue Readers and, to a lesser extent, Cue Control Swab Packs. While the U.S. DoD agreement is for a fixed volume of Cue Readers, Cue Test Kits and Cue Control Swab Packs, for other customers those products are generally sold unbundled, with Cue Test Kits sold in packs of 10. Going forward, we continue to expect product revenue to be dominated by the sale of Cue Test Kits, though we expect the proportion of product revenue coming from Cue Readers to increase as we place more of them in the home where they will likely have lower Cue Test Kit pull-through than those in the hands of the public sector, testing administrators or health care providers. Beginning in 2021, we started offering customers a subscription-based purchasing option. Subscription-based customers can initially purchase a fixed number of Cue Readers at the start of the contract and commit to a fixed number of Cue Test Kits per month for the duration of the subscription agreement. We believe our subscription-based model offers customers maximum utility and allows them to reduce their purchase costs, while simultaneously creating a recurring revenue stream for us. Going forward, we may offer alternate forms of subscription or bundling of products as our product offering expands. Revenue generated from customers with subscription-based contracts was $29.8 million during the six months ended June 30, 2021 (of which $28.9 million was derived from a single enterprise customer). We also provide our Cue Health App to all customers as well as other software to organizations, including the Cue Enterprise Dashboard and the Cue Data and Innovation Layer. Currently, all of our software products are available at no cost, though we may charge for these offerings as we increase functionality and expand our offerings in the future. Beyond product revenue we may also generate grant and other revenue which may be more variable and in 2020 was exclusively linked to our contract with the U.S. Biomedical Advanced Research and Development

Authority, or BARDA, a division of the U.S. HHS. We did not generate any grant or other revenue during the six months ended June 30, 2021. Going forward we expect to continue to seek these sources of revenue both as a source of funding for research and development and as an opportunity for collaboration with strategic partners.

We plan to drive our future revenue growth through, among other means:

Increasing the Number of Cue Readers and Cue Test Kits Shipped: The placement of Cue Readers is critical to the adoption of our platform and products. We view the number of Cue Readers shipped to both existing and new customers to be a leading indicator of the long-term opportunity for widespread adoption of our platform and potential pull-through demand for our current and future tests. As of August 31, 2021, we have shipped over 115,000 Cue Readers and over five million Cue Cartridges, which have been deployed to over 280 school districts, nursing homes, hospitals, public health facilities and organizations, essential businesses, correctional facilities, other public sector users, enterprise customers and healthcare providers. We are focused on continuing to significantly increase our placement of Cue Readers to help drive adoption of our platform and sales of Cue Test Kits.

Expanding Our Future Care Offerings: Our ability to successfully develop and commercialize additional tests for our platform is also a key component to our future success. In addition to our FDA-authorized COVID-19 test, we currently have five tests in late-stage technical development. We believe the flexibility of our platform will allow us to develop and commercialize a wide range of tests for a number of different indications and uses, including respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management, with several of these tests expected to be submitted for FDA authorization or clearance by the end of 2022.

Integrating Our Cue Enterprise Dashboard with Healthcare and Telemedicine Providers and EMR Systems: In July 2020, we launched our web-based Cue Enterprise Dashboard, which has been used by many of our key customers such as the Mayo Clinic and the National Basketball Association. We are continuously working to expand the capabilities and improving the features of the Cue Enterprise Dashboard with a view towards driving further usage and adoption by existing and new customers. We have also developed integrations with leading EMR systems such as Epic. We believe these integrations will increase the value of our solutions, which we believe will ultimately lead to higher levels of adoption of these solutions and allow our customers to easily incorporate our Cue Enterprise Dashboard into their existing process, allowing for improved patient monitoring, intelligence and reporting and more efficient enterprise level health management. In addition, we also seek to drive utilization of our Cue Enterprise Dashboard by healthcare providers, including telehealth providers, to further expand our commercial opportunity.

Our U.S. DoD agreement formed a key component of our initial go-to-market strategy. Funds received under our U.S. DoD agreement allowed us to accelerate commercialization of our COVID-19 test, quickly scale up our manufacturing capabilities and provided us with a significant initial source of product revenue. In addition, through our U.S. DoD agreement, the U.S. government has placed Cue Readers with end users that represent potential new direct customer opportunities for us. Demand for our Cue Readers and COVID-19 Test Kits currently exceeds our manufacturing capacity. As a result, and considering our existing commitments under the U.S. DoD agreement and to our other existing customers, we are strategically selecting customers based on select criteria including order volume, industry diversification and potential interest in our broader anticipated future test menu.

Our direct sales team is comprised of experienced sales professionals focused on the following four categories:

- ***Public Sector Sales:*** Our public sector sales team identifies new opportunities within federal, state and local government agencies. While we expect that revenue from other categories of customers will become a larger component of our revenue over time, our public sector sales strategy continues to look to identify new opportunities within federal, state and local government agency customers.
- ***Enterprise Sales:*** Our enterprise sales team identifies major self-insured enterprises, such as Fortune 500 companies with large, covered employee populations, as well as small-to-medium sized businesses with healthcare plan partners and employee benefits offerings. We believe that enterprise customers will want to utilize our integrated care solutions for their employees and their families, both on-premises and at-home.
- ***Healthcare Provider Sales:*** Our healthcare provider sales team identifies and targets major healthcare systems and healthcare providers such as hospital systems, clinic networks, concierge health systems and physicians' offices. Relationships with our healthcare provider customers, such as our current relationship with the Mayo Clinic, help validate our platform, and we believe will help accelerate marketplace adoption of our products.

- ***Direct-to-Consumer Sales:*** Our direct-to-consumer sales team identifies opportunities through online and offline retail channels such as e-commerce and in-store sales.

We also have a distribution agreement with Henry Schein, Inc., or Henry Schein, pursuant to which Henry Schein acts as our exclusive distributor in the dental market and non-exclusive distributor in other markets as well as non-exclusive distribution agreements with Medline and Avantor / VWR.

Our customer agreements contain standard commercial terms and conditions and include payment terms, quantities, billing frequency, warranties and indemnification. Beginning in 2021, we started offering customers a subscription-based purchasing option. Subscription-based customers can initially purchase a fixed number of Cue Readers at the start of the contract and commit to a fixed number of Cue Test Kits per month for the duration of the subscription agreement. We believe our subscription-based model offers customers maximum utility and allows them to reduce their purchase costs, while simultaneously creating a recurring revenue stream for us.

We believe focused efforts on each of our customer segments is critical given the unique role each plays in the healthcare ecosystem, the total size of their respective addressable markets and the potential benefits that each receive from our platform. Although our initial focus is driving adoption of our Cue Readers and our COVID-19 Test Kits, we are educating all our current and prospective customers about the broad applicability of our platform and the potential rollout of our broader test menu. We believe every placement of a Cue Reader creates a durable, lasting installed base for our broader test menu to serve.

Our automated manufacturing process to produce Cue Cartridges was developed in tandem with our platform technology and is designed to be flexible and quickly scalable. Each manufacturing line is built as a self-contained pod and can produce any of the Cue Cartridges contemplated as part of our planned test menu. In addition, we produce all of our biochemistry in-house, including enzymes, antibodies and primers. We believe this combination of flexible, scalable manufacturing and in-house reagent production allows us to not only scale quickly but also adapt our production quickly to market demands or evolving consumer needs. Production of our Cue Readers is performed for us by third-party contract manufacturers, while production of our Cue Wands is performed by both us and by third-party contract manufacturers. For our Cue Readers and Cue Wands, we own and control all of the intellectual property developed by us and rely on multiple suppliers.

During the fall of 2020 we launched a significant expansion of our manufacturing capacity, leasing two additional facilities, our approximately 197,000 square foot Vista facility and our approximately 63,000 square foot Waples facility. These additional facilities have allowed, and we expect will further allow us to further expand our reagent production and cartridge manufacturing, bring additional cartridge component manufacturing in-house, and improve our distribution capabilities. As of August 31, 2021, the Vista facility was producing cartridges from six production pods (with dedicated space for an additional four production pods) and was serving as our warehousing and distribution hub. Our Waples facility will serve as a second reagent production hub, house certain cartridge component manufacturing, and has dedicated space for five production pods, all of which are currently in operation. Our Nancy Ridge facility is also producing cartridges from two production pods. We believe our existing manufacturing footprint is sufficient to meet our current needs and planned manufacturing expansion for the foreseeable future, and that we will be able to find appropriate space for expansion when needed in the future.

Certain Key Factors Affecting Our Performance

The performance of our business depends on a number of factors, including the key factors discussed below. While each of these areas presents significant opportunities for us, they also pose challenges and risks that we must address to sustain the growth of our business and improve our results of operations. See the section titled “Risk Factors” for additional information on the various challenges and risks we face as we look to grow our business and become profitable.

U.S. Department of Defense Agreement

In October 2020, we entered into a $480.9 million agreement with the U.S. DoD, or the U.S. DoD agreement, to expand our U.S.-based production capacity, to deploy 6,000,000 COVID-19 Test Kits, 30,000 Cue Readers and 60,000 Cue Control Swab Packs (which include three negative and three positive control swabs per pack) by April 2021. We received $184.6 million of the $480.9 million agreement amount, or the U.S. DoD Advance, at the time of signing the agreement, with the initial payment meant to facilitate the scaling of our manufacturing. This payment was intended to help us onshore our supply chain and rapidly increase our production capacity to enable and

support domestic production of critical medical resources. The remaining $296.3 million under the agreement was committed to the federal government's purchase of Cue Test Kits, Cue Readers and Cue Control Swab Packs under the agreement, with payment to be received against shipments of product at agreed upon pricing. For the six months ended June 30, 2021, we received cash payments of $114.3 million under the U.S. DoD agreement.

In March 2021, the U.S. DoD agreement was amended to, among other things, allow for additional ramp-up time and for delivery of the 6,000,000 COVID-19 Test Kits and other deliverables to be made by October 12, 2021 and in September 2021, that date was extended to December 31, 2021. To satisfy the terms of the arrangement, we are obligated to provide the U.S. government with the COVID-19 Test Kits, Cue Readers and Cue Control Swab Packs pursuant to a specified delivery schedule and demonstrate our ability to manufacture a sustained average of approximately 100,000 COVID-19 Test Cartridges per day over a consecutive seven-day period by December 31, 2021. Subject to exceptions, the U.S. government is entitled to be the exclusive purchaser of our entire production through the completion of the project. Pursuant to the U.S. DoD agreement, we are permitted to honor certain contractual obligations that existed prior to the effective date of the U.S. DoD agreement and may use a reasonable number of tests for internal workforce testing as well as for marketing, demonstration and evaluation of our products and business development. Furthermore, we have, and can seek additional, waivers from the U.S. government to sell certain of our products to additional customers. In April 2021, we received a waiver from the U.S. DoD, or the U.S. DoD Waiver, effective May 1, 2021, allowing us to distribute commercially up to 50% of our COVID-19 Test production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. We anticipate that the U.S. DoD Waiver will remain in effect for the duration of the U.S. DoD agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements. Per ASC Topic 606, the initial payment from the U.S. DoD agreement was recorded in deferred revenue. Deferred revenue will be recognized proportionally to product shipments in the current agreement and a follow-on contract. Due to management estimates related to the size and delivery schedule of a follow-on contract relative to the size of the initial agreement we expect recognition of deferred revenue related to the initial agreement to decline following final delivery of the products in the initial agreement.

For at least the duration of the initial U.S. DoD agreement, we expect that at least 50% of our manufacturing capabilities will be dedicated to meet the demand from the U.S. DoD agreement, per the terms of the U.S. DoD waiver. As a result, our ability to acquire new customers will be constrained and we expect to be unable to satisfy much of the non-U.S. government demand for our products during this time. The U.S. DoD agreement also provides that, as soon as possible after the initial U.S. DoD agreement, we and the U.S. government are expected to negotiate in good faith to enter into a follow-on supply agreement based on federal acquisition regulations (a FAR-based contract). The future-contract would provide the U.S. DoD with the right to purchase up to 45% of our quarterly production for the duration of the contract at a percentage discount in the low teens to the lowest price offered by us to a commercial customer for the same products, equivalent quantities and comparable terms of sale, subject to a minimum price floor. Any such additional contract with the U.S. government could constrain our ability to grow our business with non-U.S. government customers.

As of August 31, 2021, we had delivered all of the Cue Readers and over three and a half million Cue Covid-19 Test Kits pursuant to the U.S. DoD agreement. As of August 31, 2021, our daily manufacturing capacity was on average over 43,000 Cue Test Kits per day over a seven-day period, with a single day peak of nearly 60,000 COVID-19 Test Kits, and we are continuing to add daily capacity to meet our obligations under the U.S. DoD agreement. Until we can diversify our customer base, the success of our business depends in large part on our ability to fulfill our obligations under the U.S. DoD agreement and any future related contract. Among other things, upon conclusion of the U.S. DoD agreement, we anticipate that our revenue may decline significantly, at least in the short term (if not longer).

Expanding Our Manufacturing Capacity

The growth of our business depends on our ability to rapidly expand our current manufacturing capacity to meet the demand for our platform and tests, in particular our COVID-19 test, since at least 50% of our current production capacity is dedicated to fulfilling our current contractual obligations under the U.S. DoD agreement. We manufacture all of our Cue Cartridges in our vertically integrated facilities in San Diego, California. We also produce all of our biochemistry in-house, including critical enzymes, antibodies and primers for our Cue Cartridges. Production of our Cue Readers is performed for us by third-party contract manufacturers and production of our Cue Wands is performed by both us and by third-party contract manufacturers.

We are currently scaling our manufacturing capabilities, including our fully automated production pods, to be able to produce approximately 100,000 COVID-19 Cartridges per day, consistent with our obligations under the U.S. DoD agreement, by December 31, 2021. A production pod is a free standing, modular environmentally controlled structure containing an automated cartridge production line. Our current manufacturing facilities can accommodate up to 17 production pods. In October 2020, we had one active production pod. As of August 31, 2021, we had 13 active production pods. We expect that an additional production pod will be completed by the end of 2021. We expect that the development of our manufacturing facilities will be funded by our available cash resources, including the proceeds from this offering and cash on hand. As we expand our manufacturing capacity, we expect to see a reduction in per unit manufacturing costs in 2021 and thereafter.

Investments in Our Growth

We expect to make continued significant investments in our business to drive growth, and therefore we expect our expenses to increase going forward. We expect to invest significant resources in sales and marketing to drive demand for our products and services as well as research and development to enhance our platform and bring additional tests to market. We also intend to continue investing in our supply chain and logistics operations. As we continue to scale our business, we expect to hire additional personnel and incur additional expenses, including those expenses in connection with our becoming a public company.

Expanding Our Customer Base

The future commercial success of our diagnostic products is dependent on our ability to broaden our customer base beyond the U.S. government to markets including individuals, enterprises and healthcare providers. We believe demand for our diagnostic products from all customer channels exceeds our current production capacity. In addition, as discussed above, a substantial portion of our current production capacity is dedicated to fulfilling our contractual obligations under the U.S. DoD agreement and our U.S. DoD agreement currently limits our ability to significantly expand our customer base. The U.S. DoD agreement gives the U.S. DoD the right to negotiate with us for a follow-on supply FAR-based contract which, if entered into, would require us to sell up to 45% of our quarterly production capacity to the U.S. DoD, which may further limit our ability to expand our customer base. In addition to the U.S. DoD, other current key strategic relationships include the U.S. Biomedical Advanced Research and Development Authority, or BARDA, Google LLC, or Google, the Mayo Clinic, the National Basketball Association, and Henry Schein, Inc. We believe that there is substantial market opportunity for our consumer-oriented diagnostic testing platform that sits at the nexus of healthcare and technology and that allows for clinical lab quality molecular diagnostic testing of individuals at home, at the point-of-care, in the workplace and in other settings, and on an over-the-counter basis. We intend to leverage our success with our COVID-19 Test and the expansion of our manufacturing capabilities to enable broad distribution of our Cue Readers and awareness of our platform across different groups of customers and to enhance pull-through of our future tests.

Enhancing and Expanding Our Menu of Tests and Software Capabilities

Currently, our only commercially available test is our molecular COVID-19 test. A key part of our growth strategy is to expand our menu of tests to include other diseases, ailments and general health markers, which we expect will support our growth and continue to contribute to the utility of our platform, including the Cue Health Monitoring System. We are currently developing tests in the fields of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management, with several of these tests expected to be submitted to the FDA for authorization or clearance by the end of 2022, at the earliest.

As we continue to develop and expand our menu of tests, we have made, and will continue to make, significant investments in our business, particularly in research and development, sales and marketing and the hiring of additional personnel. Investing in research and development will allow us to develop new tests as well as enhance our current product offerings and our Cue Integrated Care Platform. To build out our menu of tests and bring additional products to market, we will need to hire additional personnel, such as engineers and researchers, as well as develop robust sales and marketing and customer support teams to be able to sell our products.

Regulatory Clearance of Our Diagnostic Products

Our commercial success will depend upon a number of factors, some of which are beyond our control, including the receipt of regulatory clearances, approvals or authorizations for existing or new product offerings by us, product enhancements, or additions to our proprietary intellectual property portfolio. While we have received two EUAs for

our COVID-19 test, a CE mark in the European Union, an Interim Order authorization from Health Canada, and regulatory approval from CDSCO, our COVID-19 test has not been FDA cleared or approved and is only authorized for emergency use during the declaration that circumstances exist justifying the authorization of emergency use, and this declaration could be terminated, or our authorization could be revoked in the future. We will need to seek additional regulatory approval for our COVID-19 test if the EUA declaration or Interim Order is terminated or otherwise revised or revoked, and we will need to seek regulatory authorization, clearance or approval for our other diagnostic products in development. In addition, we will not be able to commercialize any other tests for our platform unless we obtain required regulatory clearances or other necessary approvals or authorizations. There are numerous factors associated with the successful development of any diagnostic product and obtaining regulatory clearance or other necessary approvals or authorizations. After a device or other product is cleared, approved or authorized for marketing, numerous and pervasive regulatory requirements continue to apply. As such, our ability to navigate, obtain and maintain the required regulatory clearances, approvals or authorizations, as well as comply with other regulatory requirements, for our products will in part drive our results of operations and impact our business. See the section titled “Our Business—Government Regulation” for further discussion.

Reimbursement and Insurance Coverage

We have been granted two EUAs by the FDA for our COVID-19 test for point-of-care and at-home and over-the-counter indications. The commercial success of our COVID-19 test, and any of our subsequently developed tests, is dependent on a customer’s ability to be able to pay for or otherwise be reimbursed for the purchase of a test, whether out-of-pocket, by insurance or from a governmental or other third-party payor. We believe payment for our products, including our COVID-19 Test Kits, will be billable by a physician, reimbursable by government payors or insurance companies, paid for by a self-insured employer, or eligible under FSA and HSA guidelines. For example, most of our contemplated future tests that are currently offered by others through central labs are reimbursable by health plans and governmental payors if properly ordered by a physician. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Coverage criteria and reimbursement rates for clinical laboratory tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future. We believe that the benefits of our portable, intuitive, accurate and connected system align incentives for all stakeholders, the user and the payors (self-insured employers and health plans), and that this will encourage payors to pay for or subsidize the Cue Health Monitoring System and associated tests for the end-user. Ultimately, however, if the Cue Health Monitoring System, including any of our current or future tests, are not reimbursable or covered by insurance, our business may be materially and adversely impacted.

Seasonality

We anticipate that fluctuations in customer and user demand for our COVID-19 test may be similar to those related to influenza, which typically increases during the fall and winter seasons. Although our products will be available throughout the year, we anticipate that we may experience higher sales during the fall and winter seasons, relative to the spring and summer seasons. However, as our portfolio of diagnostic offerings increases beyond our COVID-19 test, we expect the impact of this seasonality on our results to decrease.

COVID-19 Impact

While the ongoing global COVID-19 pandemic has adversely impacted global commercial activity, it served as a catalyst to accelerate our product pipeline and commercialization of our platform. We began selling and recording product revenue for our COVID-19 test in August 2020 after obtaining our first FDA EUA in June 2020. Currently, 100% of our product revenue is related to sales of our COVID-19 test.

In December 2020, the FDA issued EUAs for two COVID-19 vaccines and in February 2021, the FDA issued a third EUA for a COVID-19 vaccine. In August 2021, the FDA granted full approval for one of the previously authorized COVID-19 vaccines. The widely administered use of an efficacious vaccine or the availability of therapeutic treatments for COVID-19 may reduce the demand for our COVID-19 test and could cause the COVID-19 diagnostic testing market to fail to grow or to decline. However, we believe the need for ongoing detection and monitoring will continue to be high even after effective vaccines have been widely distributed and administered. We also believe COVID-19 will remain endemic for the foreseeable future and people suspected of COVID-19 will want to obtain a fast and accurate COVID-19 test to confirm a diagnosis in order to receive timely and appropriate treatment. Even while vaccine efforts are underway, public health measures, like testing, will likely need to stay in effect to protect against COVID-19. However, given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

Components of Our Results of Operations

Revenue

Product Revenue. Our product revenue currently only relates to sales of our COVID-19 test, which began in August of 2020 after we obtained our initial EUA in June of 2020. With respect to the U.S. DoD agreement, the transaction price is fixed and does not include variable consideration. The U.S. DoD Advance of $184.6 million was recorded as deferred revenue and will be recognized upon satisfaction of performance obligations, such as the delivery of Cue Cartridges, Cue Readers, Cue Wands and Cue Control Swab Packs to the U.S. government. Significant judgment is applied in determining how deferred revenue will be recognized, including estimating future quantities, delivery schedules, pricing and contract duration from the U.S. government, which can have a significant impact on revenue recognition. Deferred revenue related to the U.S. DoD Advance as of June 30, 2021 was $140.1 million. Of this amount, $93.3 million was classified as current as of June 30, 2021, based on amounts expected to be realized within the next twelve months. Deferred revenue related to the U.S. DoD Advance as of December 31, 2020, was $182.3 million. Of this amount, $114.9 million was classified as current at December 31, 2020, based on amounts expected to be realized during 2021. The remaining $164.8 million of contract value under the U.S. DoD agreement, excluding deferred revenue, that had not been paid to us as of June 30, 2021, is expected to be recognized by us as revenue upon satisfaction of performance obligations by reference to the total products expected to be provided under the U.S. DoD agreement, including an estimate of future performance obligations under expected contract renewals, and the corresponding expected consideration. Upon final delivery of products specified in the current U.S. DoD agreement, we expect a reduction in the recognition of deferred revenue related to the U.S. DoD Advance, and a related negative impact to product revenue growth, as a larger proportion of product sales go to other customers. Commercial customers outside of the U.S. government accounted for approximately 17% of our product revenue for the six months ended June 30, 2021. Of this amount, a single enterprise customer accounted for $28.9 million of revenue during this period. Revenue from commercial customers increased sequentially from 4% for the three months ended March 31, 2021, to 24% for the three months ended June 30, 2021 (with a single enterprise customer accounting for a substantial portion of the increase). While at least 50% of our production capacity in 2021 is expected to be dedicated to fulfilling our obligations under the U.S. DoD agreement, we expect to continue to grow our revenue from non-government customers over time. Upon conclusion of the U.S. DoD agreement, we anticipate that our revenue may decline significantly (at least in the short term, if not longer), and that we will be largely dependent on new and other existing customers for our revenue at such time.

In April 2021, we started offering non-government customers a subscription-based purchasing option. Subscription-based customers can initially purchase a fixed number of Cue Readers at the start of the contract and commit to a fixed number of Cue Cartridges per month for the duration of the subscription agreement. We believe our subscription-based model offers customers maximum utility, while simultaneously creating a recurring revenue stream for us. Revenue generated from customers with subscription-based contracts was $29.8 million during the three months ended June 30, 2021 (with a single enterprise customer accounting for a $28.9 million of this amount).

Grant and Other Revenue. Our grant and other revenue primarily relate to our cost reimbursement research and development agreement with BARDA, which, as amended, is effective through January 2022 for phase one and through January 2023 for phase two. The objective of the contract is to accelerate the development, validation and FDA clearance of our influenza and COVID-19 diagnostic products. We have received $35.5 million in contracts and awards, $21.8 million for phase one and $13.7 million for phase two, from BARDA from June 2018 to June 30, 2021. Income derived from reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with U.S. government contracts are recorded as grant revenue. We recognize revenue from our contracts and awards with BARDA at the gross amount of the reimbursement in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory performance obligations are outstanding. Grant and other revenue in 2019 also included $0.4 million related to our collaboration agreement with Janssen Pharmaceuticals, Inc, or the Janssen Contract. We did not recognize any revenue related to the Janssen Contract in 2020 and do not expect to recognize significant revenue under the Janssen Contract in 2021. The direct costs associated with both contracts are reflected as a component of research and development expense in our statements of operations.

Operating Costs and Expenses

Cost of Product Revenue. Our cost of product revenue includes the cost of materials, direct labor, and manufacturing overhead costs used in the manufacture of our Cue Cartridges as well as contract manufacturing costs associated with production of our Cue Readers, Cue Wands and Cue Control Swab Packs. During the six months ended June 30, 2021,

we identified certain immaterial amounts that were previously capitalized as intangible assets and we recorded these amounts as incremental amortization expense within cost of product revenue. Prior to August 2020, we had not commenced sales of our diagnostic products and as such, did not record any cost of product revenue. We expect that our cost of product revenue will increase on an absolute basis for the foreseeable future as we continue to grow and sell a higher volume and wider variety of our diagnostic products. We expect that the cost per Cue Cartridge will decrease over time due to the increase in the number of production pods, the reduction of scrap, volume efficiencies across the supply chain on materials and shipping costs, the transition of certain production capabilities to be handled in-house, and through other efficiencies we may gain as manufacturing of reagents increases.

Sales and Marketing Expense. Our sales and marketing expense consists primarily of salaries and other related costs for personnel in sales and marketing, customer support and business development functions as well as advertising and marketing costs. We expect that our sales and marketing expense will increase significantly on an absolute dollar basis and vary from period to period as a percentage of revenue for the foreseeable future as we focus on building out our customer facing organization and expand our brand.

Research and Development Expense. Research and development expenses consist of external and internal costs associated with our research and development activities, including costs associated with developing our platform, the individual tests we offer on our platform and clinical and regulatory costs associated with obtaining regulatory approval for those tests. Our research and development expenses include:

- external costs, including expenses incurred under arrangements with third parties, primarily associated with CROs performing clinical studies and regulatory submissions; and
- internal costs, including:
  - employee-related expenses, including salaries, benefits, and stock-based compensation;
  - the costs of laboratory supplies, research materials and Cue Cartridges we produce for research and development purposes; and
  - facilities, equipment, and information technology, which include depreciation and amortization costs, direct and allocated expenses for rent and maintenance of facilities and equipment.

Costs associated with our U.S. government agreements and our collaboration contracts (including our contracts with BARDA and Janssen, respectively) are recorded within research and development expense. We expense research and development costs in the periods in which they are incurred.

At any given time, we are working on multiple programs, including specific tests and other components of the platform. Our internal resources, employees and infrastructure are not directly tied to any one program or test and there is often significant overlap in research and development efforts between different programs and tests and we are often able to leverage the research and development of one test or program to help advance one or more other programs or tests. As such, we do not track internal costs on a test-by-test basis. The following table summarizes our external and internal costs for the periods presented:

	Year Ended December 31,		Six Months Ended June 30,	
	2019	2020	2020	2021
(dollars in thousands)			(unaudited)	
External costs	$ 1,534	$ 4,441	$ 2,859	$ 1,474
Internal costs				
Salaries and benefits	8,366	7,607	4,428	3,751
Facilities and supplies	11,505	16,430	12,393	6,846
Total internal costs	19,871	24,037	16,821	10,597
Total research and development expense	$21,405	$28,478	$19,680	$12,071

The primary focus of our research and development effort has evolved over time. The work to get certain of our tests into the late-stage technical development phase for the general immunoassay modality and certain specific immunoassays (including fertility, pregnancy, and inflammation) was largely complete prior to a shift of our focus in mid-2018. At that time, we refocused our efforts on improving the NAAT modality within our platform and completing our first automated production line, initially used to build Cue Cartridges for research and development purposes. The primary target within NAAT from mid-2018 was respiratory infectious disease testing, in particular, influenza. The focus on influenza (which also helped advance our very similar RSV test) lasted until COVID-19 came to the forefront in early 2020. Research and development efforts shifted fully to developing our COVID-19 test in March of 2020 when our clinical study sites for influenza were closed to those with respiratory illness symptoms due to the COVID-19 pandemic. COVID-19 remained our focus through most of 2020. Starting in early 2021, we began to shift our research and development efforts to finalizing our tests in late-stage technical development and restarting development on tests in earlier stages. We expect that our research and development expense will increase significantly on an absolute dollar basis and vary from period to period as a percentage of revenue for the foreseeable future as we continue to invest in development activities related to our technology platform and our current and future test menus and continuing to expand our portfolio of diagnostic testing offerings.

General and Administrative Expense. Our general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate development and administrative functions. General and administrative expense also includes professional fees for legal, patent, accounting, information technology, auditing, tax and consulting services, travel expenses and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. We expect that our general and administrative expense will increase on an absolute dollar basis and vary from period to period as a percentage of revenue for the foreseeable future as we focus on processes, systems and controls to enable our internal support functions to scale with the growth of our business. We expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, costs related to compliance with the rules and regulations of the Securities and Exchange Commission and exchange listing standards, higher director and officer insurance costs, and investor and public relations costs.

Interest Expense. Our interest expense prior to February 2021 primarily consists of expense related to our prior loan and security agreement with Comerica Bank. In February 2021, we entered into a new loan and security agreement with East West Bank and the other lenders party thereto. In May 2021, we repaid $63.2 million outstanding under the Revolving Credit Agreement with a portion of the net proceeds from the issuance and sale of the Convertible Notes. In June 2021, we terminated the Revolving Credit Agreement. See “Liquidity and Capital Resources” below.

Change in Fair Value of Redeemable Convertible Preferred Stock Warrants. Change in fair value of redeemable convertible preferred stock warrants relates to our liability-classified redeemable convertible preferred stock warrants which are recorded on the balance sheets at their fair values on the date of issuance and are revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statements of operations.

Change in Fair Value of Convertible Notes. Change in fair value of convertible notes relates to our liability-classified convertible notes which are recorded on the balance sheets at their fair values on the date of issuance and are revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statements of operations.

Results of Operations

The following table sets forth a summary of our results of operations for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2019	2020	2020	2021
(dollars in thousands)			(unaudited)	
Revenue:				
Product revenue	$ —	$ 15,391	$ —	$201,922
Grant and other revenue	6,626	7,562	4,960	—
Total revenue	6,626	22,953	4,960	201,922
Operating costs and expenses:				
Cost of product revenue(1)(2)	—	14,951	—	85,177
Sales and marketing(1)	88	714	45	1,959
Research and development(1)	21,405	28,478	19,680	12,071
General and administrative(1)	5,900	23,936	3,764	23,252
Total operating costs and expenses	27,393	68,079	23,489	122,459
Income (loss) from operations	(20,767)	(45,126)	(18,529)	79,463
Interest expense	(152)	(984)	(788)	(9,964)
Change in fair value of redeemable convertible preferred stock warrants	4	(1,289)	(20)	(190)
Change in fair value of convertible notes	—	—	—	(23,254)
Other income (expense), net	309	47	59	61
Net income (loss) before income taxes	(20,606)	(47,352)	(19,278)	46,116
Income tax expense	—	—	—	(13,276)
Net income (loss)	$(20,606)	$(47,352)	$(19,278)	$ 32,840

(1) Includes stock-based compensation expense as follows: during the six months ended June 30, 2021, $0.1 million of stock-based compensation expense was capitalized to inventory during the manufacturing process.

	Year Ended December 31,		Six Months Ended June 30,	
	2019	2020	2020	2021
(dollars in thousands)			(unaudited)	
Cost of product revenue	$ —	$ —	$—	$ 343
Sales and marketing	—	1	—	26
Research and development	45	98	13	1,444(3)
General and administrative	291	3,064	84	3,778
Total stock-based compensation expense	$336	$3,163	$97	$5,591

(2) Includes $2.1 million and $10.5 million of depreciation and amortization expense for the year ended December 31, 2020, and for the six months ended June 30, 2021, respectively.

(3) Includes $1.2 million of stock-based compensation related to a common stock warrant exercised by a vendor.

Depreciation and amortization expense was reclassified to research and development and general and administrative expenses for the years ended December 31, 2019 and 2020.

Comparison of the Six Months Ended June 30, 2020 and 2021

The following table sets forth a summary of our results of operations for the years ended June 30, 2020 and 2021 and the changes between periods:

	Six Months Ended June 30,			
	2020	2021	$ Change	% Change
(dollars in thousands)	(unaudited)			
Revenue:				
Product revenue	$ —	$201,922	$201,922	n.m.
Grant and other revenue	4,960	—	(4,960)	(100.0)%
Total revenue	4,960	201,922	196,962	n.m.
Operating costs and expenses:				
Cost of product revenue	—	85,177	85,177	n.m.
Sales and marketing	45	1,959	1,914	n.m.
Research and development	19,680	12,071	(7,609)	(38.7)%
General and administrative	3,764	23,252	19,488	517.7%
Total operating costs and expenses	23,489	122,459	98,970	421.3%
Income (loss) from operations	(18,529)	79,463	97,992	528.9%
Interest expense	(788)	(9,964)	(9,176)	n.m.
Change in fair value of redeemable convertible preferred stock warrants	(20)	(190)	(170)	n.m.
Change in fair value of convertible notes	—	(23,254)	(23,254)	n.m.
Other income (expense), net	59	61	2	3.4%
Net income (loss) before income taxes	(19,278)	46,116	65,394	339.2%
Income tax expense	—	(13,276)	(13,276)	n.m.
Net income (loss)	$(19,278)	$ 32,840	$ 52,118	270.3%

n.m. = not meaningful

Revenue increased by $197.0 million to $201.9 million in the six months ended June 30, 2021, from $5.0 million in the six months ended June 30, 2020. This increase was due to the start of product sales in August 2020. Of the $201.9 million of product revenue recorded in the six months ended June 30, 2021, $159.7 million related to sales of our COVID-19 test and $42.2 million was related to the amortization of the U.S. DoD Advance. Revenue increased by $72.9 million in the three months ended June 30, 2021, to $137.4 million, compared sequentially to $64.5 million in the three months ended March 31, 2021. The increase of $72.9 million was due to an increase of commercial customer sales of $30.0 million (of which $28.9 million was attributable to a single enterprise customer) and an increase in U.S. government revenue of $42.9 million in the three months ended June 30, 2021 compared to the three months ended March 31, 2021. The amortization of the U.S. DoD Advance increased by approximately $10.9 million in the three months ended June 30, 2021 compared to the three months ended March 31, 2021 due to increased volume of products sold under the U.S. DoD Agreement as pricing and total expected contract value were materially consistent. The increase in commercial customer revenue and subsequent decrease in U.S. government revenue in this period were driven by the U.S. DoD Waiver allowing us to increase sales to commercial customers beginning in May 2021. The increase in our revenues in the three months ended June 30, 2021 compared to March 31, 2021 was primarily driven by increased sales volume of our COVID-19 Test Kits and Readers to the U.S. government and our commercial customers.

Grant and other revenue decreased by $5.0 million, to $0 in the six months ended June 30, 2021, from $5.0 million in the six months ended June 30, 2020. During the six months ended June 30, 2020, all of the revenue recognized related to the agreement with BARDA. There was no activity related to this revenue category during the six months ended June 30, 2021.

Cost of Product Revenue increased by $85.2 million in the six months ended June 30, 2021, from $0 in the six months ended June 30, 2020. This increase was due to the fact that we did not incur cost of product revenue until we began to generate product revenue in August 2020 after receiving our first FDA EUA in June 2020. Product gross profit was $116.7 million in the six months ended June 30, 2021, up from $0 in the six months ended June 30, 2020,

as we did not incur cost of product revenue prior to receipt of our first EUA. During the six months ended June 30, 2021, we identified certain immaterial amounts that were previously capitalized as intangible assets. These amounts were recorded as incremental amortization expense during the six months ended June 30, 2021 and recorded as cost of product revenue. Our cost of product revenue increased by $25.1 million in the three months ended June 30, 2021 to $55.1 million compared sequentially to $30.0 million in the three months ended March 31, 2021. This increase of $25.1 million was due to increased production and sales volume to commercial customers resulting from the U.S. DoD Waiver in the three months ended June 30, 2021 compared to the three months ended March 31, 2021. Our product gross profit margin, or product gross profit as a percentage of product revenue, increased to approximately 59.9% in the three months ended June 30, 2021 compared to approximately 53.4%, in the three months ended March 31, 2021. This increase was primarily due to higher absorption of fixed costs related to higher production volumes and efficiencies. DoD revenue pricing, inclusive of the DoD advance and related amortization recognized upon sale, was consistent quarter over quarter and the increase is directly related to the volume of products sold under the U.S. DoD Agreement.

Sales and Marketing Expense increased by $1.9 million in the six months ended June 30, 2021, to $2.0 million from an immaterial amount in the six months ended June 30, 2020. This increase was due to the launch of our COVID-19 test in August 2020 and increased personnel costs to support the expected growth and demand for our products. Our sales and marketing expense increased by $1.1 million in the three months ended June 30, 2021, to $1.5 million compared sequentially to $0.4 million in the three months ended March 31, 2021. This increase was primarily due to increases in digital marketing services and increased headcount in the three months ended June 30, 2021 compared to the three months ended March 31, 2021.

Research and Development Expense decreased by $7.6 million to $12.1 million in the six months ended June 30, 2021, from $19.7 million in the six months ended June 30, 2020. This decrease was primarily driven by lower research and development spend associated with the development of our COVID-19 test and the continued shift of our manufacturing-related depreciation and amortization into cost of product revenue upon receipt of the FDA EUA for our COVID-19 test in the six months ended June 30, 2021, compared to the six months ended June 30, 2020. Our research and development expense decreased by $2.9 million in the three months ended June 30, 2021 to $4.6 million compared sequentially to $7.5 million in the three months ended March 31, 2021. The decrease of $2.9 million in research and development expense was primarily due to a decrease in lab supplies, regulatory expenses, and office rent expenses in the three months ended June 30, 2021 compared to the three months ended March 31, 2021.

General and Administrative Expense increased by $19.5 million in the six months ended June 30, 2021 to $23.3 million from $3.8 million in the six months ended June 30, 2020. This increase was primarily related to legal, banking, accounting and other consulting-related costs to support our growing business and prepare us to operate as a public company. The decrease of $0.3 million in general and administrative expense was primarily due to increases in payroll expenses, office expenses and depreciation expense offset by decreases in professional service expenses in the three months ended June 30, 2021 compared to the three months ended March 31, 2021.

Interest Expense increased by $9.2 million to $10.0 million in the six months ended June 30, 2021 from $0.8 million in the six months ended June 30, 2020. This increase was driven by the termination of our Revolving Credit Agreement, which required us to pay a fee of $1.3 million, equal to 1.00% of the amount of the outstanding revolving commitment. We also wrote-off issuance costs of $0.7 million for a total loss on extinguishment of debt of $2.0 million. In addition, we incurred issuance costs of $6.0 million related to the issuance of our Convertible Notes in May 2021. We also incurred interest expense of $1.6 million related to our borrowings from the Revolving Credit Agreement and Convertible Notes during the six months ended June 30, 2021. Interest expense increased $8.9 million in the three months ended June 30, 2021 to $9.4 million compared sequentially to $0.5 million in the three months ended June 30, 2021 compared to three months ended March 31, 2021. The $8.9 million increase in interest expense was primarily due to the issuance costs related to the Convertible Notes and the termination of the Revolving Credit Agreement in the three months ended June 30, 2021 compared to the three months ended March 31, 2021.

Change in Fair Value of Convertible Notes was $23.3 million in the six months ended June 30, 2021, reflecting a $23.3 million fair value adjustment associated with the Convertible Notes issued by us in May 2021. We did not incur any gain or loss associated with change in fair value of Convertible Notes during the six months ended June 30, 2020 or during the three months ended March 31, 2021, as the Convertible Notes were not outstanding during such periods.

Income Tax Expense increased to $13.3 million in the six months ended June 30, 2021 from $0 in the six months ended June 30, 2020, and our effective tax rate was 29% in the six months ended June 30, 2021, compared to 0% in the six months ended June 30, 2020. The increase in our provision and effective tax rate was primarily due to the current tax liability arising from an increase in income from operations which exceeded available net operating loss carryforwards and the discrete impact of the non-deductible fair value adjustment associated with the convertible notes that were issued in May 2021. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the six months ended June 30, 2021. Substantially all of our deferred tax assets continue to maintain a valuation allowance. Income tax expense increased $10.8 million in the three months ended June 30, 2021, to $12.0 million compared sequentially to $1.2 million in the three months ended March 31, 2021. The increase of $10.8 million was primarily due to the increase in net income during the period and an increase in forecasted revenue for the remainder of fiscal year 2021.

Comparison of the Year Ended December 31, 2019 and 2020

The following table sets forth a summary of our results of operations for the years ended December 31, 2019 and 2020 and the changes between periods:

	Year Ended December 31,			
	2019	2020	$ Change	% Change
(dollars in thousands)				
Revenue:				
Product revenue	$ —	$ 15,391	$ 15,391	n.m.
Grant and other revenue	6,626	7,562	936	14.1%
Total revenue	6,626	22,953	16,327	246.4%
Operating costs and expenses:				
Cost of product revenue	—	14,951	14,951	n.m.
Sales and marketing	88	714	626	711.4%
Research and development	21,405	28,478	7,073	33.0%
General and administrative	5,900	23,936	18,036	305.7%
Total operating costs and expenses	27,393	68,079	40,686	148.5%
Loss from operations	(20,767)	(45,126)	(24,359)	117.3%
Interest expense	(152)	(984)	(832)	547.4%
Change in fair value of redeemable convertible preferred stock warrants	4	(1,289)	(1,293)	n.m.
Other income (expense), net	309	47	(262)	(84.8%)
Net loss	$(20,606)	$(47,352)	$(26,746)	129.8%

n.m. = not meaningful

Depreciation and amortization expense was reclassified to cost of product revenue, sales and marketing, research and development, and general and administrative for the years ended December 31, 2019 and 2020.

Revenue increased by $16.3 million to $23.0 million in 2020 from $6.6 million in 2019. This increase was primarily due to the recognition of $15.4 million in product revenue during 2020, beginning in August 2020 after obtaining FDA EUA for our COVID-19 test in June 2020. Prior to August 2020 we did not generate product revenue. Of the $15.4 million of product revenue recorded in 2020, $2.3 million was related to the amortization of the U.S. DoD Advance, and the remainder related to sales of our Cue Readers and COVID-19 Test Kits.

Grant and other revenue increased by $0.9 million to $7.6 million in 2020 from $6.6 million in 2019. This increase was due to work associated with our original contract with BARDA, the exercise of an option in March of 2020 for a second phase to accelerate development, validation and FDA clearance of the Cue COVID-19 Test and an amendment to the initial phase of the contract in May 2020. The March 2020 phase two option exercise increased the total value of our contract with BARDA by $13.7 million with a period of performance through January 2023. The May 2020 amendment to the initial phase increased the total value of that phase by $7.8 million to $21.8 million and extended the term of that phase to January 2022. The increase in revenue from our contract with BARDA was offset by a reduction in revenue associated with a pause of work on the Janssen Contract during 2020 to focus on COVID-19.

Cost of Product Revenue increased by $15.0 million in 2020 from $0 in 2019. This increase was due to the fact that we did not incur cost of product revenue until we received our first EUA in June 2020. Product gross profit was $0.4 million in 2020 up from $0 in 2019 as we did not incur cost of product revenue prior to receipt of our first EUA in June 2020 and due to high per unit cartridge costs associated with the low levels of production and inefficiency we experienced during the early scale up in production during 2020.

Sales and Marketing Expense increased by $0.6 million in 2020 to $0.7 million from $0.1 million in 2019. This increase was due to the launch of our COVID-19 test and the ramp-up of our headcount to support the sales of our products.

Research and Development Expense increased by $7.1 million in 2020 to $28.5 million in 2020 from $21.4 million in 2019. This increase was primarily due to the development and launch of our COVID-19 test.

General and Administrative Expense increased by $18.0 million in 2020 to $23.9 million in 2020 from $5.9 million from 2019. This increase was related to a $9.0 million legal settlement of a contract dispute, increases in employee-related costs of $3.5 million and stock-based compensation expense of $2.8 million as a result of increased headcount to support our growing business, and increases in accounting, legal, and consulting fees of $2.2 million.

Interest Expense increased by $0.8 million in 2020 to $1.0 million in 2020 from $0.2 million in 2019. This increase was primarily due to a higher level of borrowing under our prior loan and security agreement with Comerica Bank and a $0.6 million loss on the extinguishment of debt upon closing of the Series C redeemable convertible preferred stock issuance in June 2020.

Change in Fair Value of Redeemable Convertible Preferred Stock Warrants increased by $1.3 million to $1.3 million in 2020 from $0 in 2019. This increase was primarily driven by a $1.3 million fair value adjustment in 2020 associated with our redeemable convertible preferred stock warrants.

Non-GAAP Financial Measures

We supplement the reporting of our financial information determined under accounting principles generally accepted in the United States, or GAAP, with the following non-GAAP financial measures: Adjusted Net Income and adjusted net income per diluted share, or Adjusted Diluted EPS. We define Adjusted Net Income (Loss) as net loss adjusted to exclude the impact of fair value changes to our Convertible Notes and banking and finance-related items as further described below, as well as the related tax effects of these items. We define Adjusted Diluted EPS as Adjusted Net Income (Loss) divided by the weighted-average number of common shares outstanding. We believe these non-GAAP financial measures provide meaningful information to assist investors and shareholders in understanding our financial results and assessing our prospects for future performance. Management believes the adjusted measures described above are important indicators of our operations because they exclude items that may not be indicative of or are unrelated to our core operating results and provide a baseline for analyzing trends in our underlying businesses. Management uses these non-GAAP financial measures for reviewing the operating results and analyzing potential future business trends in connection with our budget process on these non-GAAP financial measures. To measure earnings performance on a consistent and comparable basis, we exclude certain items that affect the comparability of operating results and the trend of earnings. These adjustments are irregular in timing and may not be indicative of our past and future performance. There were no non-GAAP adjustments to be made for the years ended December 31, 2019 and 2020.

For the Six Months Ended June 30, 2021

The Convertible Notes issued by us in May 2021 are recorded at fair value. We excluded the impact of fair value changes to arrive at Adjusted Net Income (Loss) as it is valued based on probability weighted scenarios regarding potential future financing scenarios that may not be indicative of our past and future performance and to assist in the evaluation of our current operating performance.

Banking and finance-related items consist of (i) banking and finance fees associated with the issuance of Convertible Notes; (ii) early extinguishment of debt costs; and (iii) fees associated with our termination of our Revolving Credit Agreement. Since such fees and costs can be material, are irregular and often mask underlying operating performance, we excluded such amounts for purposes of calculating Adjusted Net Income (Loss) and Adjusted Diluted EPS for the six months ended June 30, 2021, as they may not be indicative of our past and future performance and we believe excluding such amounts may assist investors in their evaluation of our current operating performance.

Because non-GAAP financial measures are not standardized, it may not be possible to compare these financial measures with other companies' non-GAAP financial measures having the same or similar names. These adjusted financial measures should not be considered in isolation or as a substitute for reported net income and net income per diluted share, the most directly comparable GAAP financial measures. Our non-GAAP financial measures are an additional way of viewing aspects of our operations when viewed with our GAAP results and the reconciliations to corresponding GAAP financial measures below.

The following table presents a reconciliation of our net income (loss) (GAAP) and Diluted EPS (GAAP) to Adjusted Net Income (Loss) (non-GAAP) and Adjusted Diluted EPS (non-GAAP), respectively:

	Six Months Ended June 30,			
	2020		2021	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
	(unaudited)			
Net income (loss)/diluted EPS	$(19,278)	$(1.21)	$32,840	$ 0.22
Fair value adjustment—convertible notes	—	—	23,254	0.19
Banking and finance-related items	—	—	7,998	0.07
Tax effects(1)	—	—	(816)	(0.01)
Adjusted Net Income (Loss)/Adjusted Diluted EPS	$(19,278)	$(1.21)	$63,276	$ 0.47

(1) Represents the tax impact with respect to the adjustments noted above. We applied an estimated annual effective tax rate of 24% to amounts deductible for tax purposes to estimate the tax effects. The fair value adjustment associated with our convertible notes and a portion of our banking and finance-related items were not deductible for income tax purposes and were excluded from the tax effects above.

Certain Expenses to be Incurred in Connection with Initial Public Offering

In connection with the completion of this offering, we expect to incur an incremental non-cash charge of $39.0 million as a result of the automatic conversion of our Convertible Notes issued in May 2021. We estimated approximately $62.3 million of discount on these notes that will be partially offset by the $23.3 million of non-cash expense relating to the change in the fair value of the Convertible Notes that was recognized in our statements of operations for the six months ended June 30, 2021. If the offering closes after September 30, 2021, we expect the total discount to be incurred in connection with the automatic conversion of the Convertible Notes upon completion of this offering would increase to $78.5 million plus accrued interest at the time of closing. We also expect to recognize approximately $14.9 million of non-cash stock-based compensation expense related to the forgiveness of certain promissory notes from our executives and the vesting of RSUs and option grants to executives and directors in connection with this offering. We expect to recognize this non-cash stock-based compensation expense in the period in which this offering is completed. Of the non-cash items described above, charges related to Convertible Notes will not be tax deductible. As a result of these non-cash charges, we may have a net loss for the quarter in which this offering is completed and for the fiscal year ending December 31, 2021.

Liquidity and Capital Resources

We measure liquidity in terms of our ability to fund the cash requirements of our business operations, including primarily working capital and capital expenditure needs to expand our production capabilities. Our principal sources of liquidity to date have included cash from operating activities, including the U.S. DoD Advance, net proceeds from the sale of our redeemable convertible preferred stock, Convertible Notes and warrants, and indebtedness. Our ability to expand and grow our business will depend on many factors, including our working capital needs and the evolution of our operating cash flows.

As of June 30, 2021, we had an accumulated deficit of $77.6 million, and cash, cash equivalents and restricted cash of $252.3 million. Restricted cash included in such amount as of June 30, 2021 was $6.0 million. For the six months ended June 30, 2021, we had net income of $32.8 million and net cash used in operations of $37.8 million. As of June 30, 2021, we had lease liabilities of $52.5 million. In February 2021, we entered into a $130.0 million loan and security agreement, or the Revolving Credit Agreement, with the lenders from time-to-time party thereto and East West Bank, as Administrative Agent and Collateral Agent for the lenders. Per the covenants of the Revolving Credit Agreement, we were required to maintain a balance of $80.0 million on deposit with East West Bank. In May 2021, we raised $229.5 million in net proceeds from the issuance and sale of Convertible Notes. In May 2021, we repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the proceeds

from the issuance and sale of the Convertible Notes. In June 2021, we terminated our Revolving Credit Agreement but kept in place our outstanding $6.0 million letter of credit with East West Bank. In July 2021, we increased our outstanding letter of credit with East West Bank to $12.0 million. In connection with such increase, our restricted cash increased to $12.0 million as of such time.

Based on our current business plan, we believe our anticipated operating cash flows, together with our existing cash and cash equivalents and net proceeds from this offering, will be sufficient to meet our working capital and capital expenditure requirements for at least the next 12 months.

We expect that our near and longer-term liquidity requirements will consist of working capital and general corporate expenses associated with the growth of our business, including, without limitation, expenses associated with scaling up our operations and continuing to increase our manufacturing capacity, sales and marketing expense associated with rollout of our over-the-counter, at home COVID-19 test to commercial customers, including directly to consumers, increasing market awareness of our platform and brand generally to individual consumers, enterprises and other target customers, additional research and development expenses associated with expanding our care offerings, expenses associated with continuing to build out our corporate infrastructure and expenses associated with being a public company. Our short-term capital expenditure needs relate primarily to the ongoing build out of our manufacturing facilities, and we expect such expenditures to continue throughout 2021. Notwithstanding potential additional capital expenditures related to levels of higher growth or potential global expansion, we expect our capital expenditures to decrease in 2022 and 2023 from 2021 levels.

We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing sooner than currently projected, which may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed may have a material adverse impact on our financial condition and our ability to pursue our business strategy. We may raise additional capital through equity or equity-linked offerings, debt financings or other capital sources, including potentially collaborations, strategic alliances, licenses and other similar arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or platform or grant licenses on terms that may not be favorable to us.

Our ability to raise additional funds may be adversely impacted by then-existing U.S. or global economic or market conditions and the disruptions to, and volatility in, the equity, credit and financial markets in the United States and worldwide, including those relating to the ongoing COVID-19 pandemic and actions taken to slow its spread, including any diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly and more dilutive. If we are not able to secure adequate additional funding when needed, we may need to re-evaluate our operating plan and may be forced to make reductions in spending, suspend or curtail our product manufacturing, planned new test and other product development programs and commercialization efforts, extend payment terms with suppliers, liquidate assets where possible, and curtail operations or potentially cease operations entirely. Having insufficient funds may also require us to relinquish rights to technology that we would otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose. The foregoing actions and circumstances could materially and adversely impact our business, results of operations and future prospects.

Revolving Line of Credit

On February 5, 2021, we entered into the Revolving Credit Agreement. In connection with our entering into the Revolving Credit Agreement, we repaid outstanding amounts of $5.4 million and terminated our prior loan and security agreement with Comerica Bank, or the 2015 Credit Agreement, that we initially entered into in May 2015. The 2015 Credit Agreement, as amended, provided for a revolving line with a credit extension of up to $4.0 million and a Growth Capital A Line with a credit extension of up to $6.0 million. The following summary of the Revolving

Credit Agreement does not purport to be complete and is qualified in its entirety by reference to the Revolving Credit Agreement, a copy of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

The Revolving Credit Agreement provided for a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit sub-facility of $20.0 million.

In June 2021, we terminated the Revolving Credit Agreement, and we were required to pay a fee of $1.3 million, equal to 1.00% of the amount of the outstanding revolving commitment. We also wrote-off issuance costs of $0.7 million for a total loss on extinguishment of debt of $2.0 million. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, we kept in place our outstanding letter of credit in the amount of $6.0 million with East West Bank, which has been cash collateralized. All other obligations under the Revolving Credit Agreement have otherwise been terminated. In July 2021, we increased our outstanding letter of credit with East West Bank to $12.0 million. In connection with such increase, our restricted cash increased to $12.0 million as of such time.

Convertible Notes

In May 2021, we issued and sold convertible promissory notes, or Convertible Notes, with a principal amount of $235.5 million and incurred $6.0 million of debt issuance costs that have been recorded in interest expense in the statements of operations. The Convertible Notes accrue interest at a simple rate of 3.0% per annum during the first 12-month period and at a simple rate of 9.0% per annum thereafter.

The Convertible Notes are only convertible upon a qualified conversion event or the occurrence of certain specified corporate transactions, such as a change of control transaction.

The Convertible Notes will be converted into shares of our common stock at the then effective conversion price in the case of a qualified going public transaction: (a) an IPO resulting in at least $50 million in proceeds, (b) a SPAC combination, or (c) a direct listing. If we close a sale of our preferred stock with gross proceeds to us of not less than $50.0 million, then the Convertible Notes, unless previously converted into shares of our common stock, will automatically convert into shares of the same class and series of our capital stock issued to investors in such equity financing. The conversion price with respect to a qualified conversion event, which would be a qualified going public transaction or a sale of our preferred stock, will incorporate the applicable discount: (i) a 20.0% discount if the qualified conversion event is consummated on or prior to September 30, 2021, and (ii) a 25.0% discount if the qualified conversion event is consummated after September 30, 2021.

In the event of certain corporate transactions prior to the conversion of the Convertible Notes or the repayment of the Convertible Notes, each purchaser, in its discretion, shall have the right either (a) to convert, effective immediately prior to the closing of the corporate transaction, all, but not less than all, of the outstanding principal amount of its Convertible Notes and all accrued and unpaid interest on such Convertible Notes immediately prior to the closing of a corporate transaction into shares of common stock at the then effective conversion price, or (b) be paid an amount equal to the sum of 1.75 times the outstanding principal amount of its Convertible Notes and all accrued and unpaid interest of such Convertible Notes immediately prior to the closing of a corporate transaction.

The Convertible Notes include customary events of default. In the event of any default under the Convertible Notes, the interest rate then in effect shall be increased by 3.0%, and then by an additional 3.0% each year thereafter, so long as such event of default continues. Unless earlier converted immediately prior to the qualified conversion event, the Convertible Notes and any unpaid accrued interest will become due in May 2023.

We elected to account for the Convertible Notes at estimated fair value pursuant to the fair value option and we record the change in estimated fair value in our statement of operations. As of June 30, 2021, the fair value of the of the Convertible Notes was $258.7 million, and we recorded a loss of $23.3 million related to the change in estimated fair value of the Convertible Notes in our statement of operations for the six months ended June 30, 2021.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		Six Months Ended June 30,	
	2019	2020	2020	2021
(dollars in thousands)			(unaudited)	
Net cash, cash equivalents and restricted cash (used in) provided by operating activities	$(12,996)	$ 92,655	$ (20,955)	$ (37,812)
Net cash, cash equivalents and restricted cash used in investing activities	(2,945)	(78,148)	(1,326)	(58,896)
Net cash, cash equivalents and restricted cash provided by financing activities	3,610	100,243	101,723	219,779
Net increase (decrease) in cash, cash equivalents and restricted cash	$(12,331)	$114,750	$ 79,442	$123,071

Cash Flows Provided by (Used in) Operating Activities

Net cash, cash equivalents and restricted cash provided by operating activities was $92.7 million in 2020, primarily reflecting receipt of the U.S. DoD Advance and increases in inventory and prepaid expenses and other current assets of $36.8 million, and $31.0 million, respectively, due to the commencement of product manufacturing and expansion of production facilities and manufacturing capacity.

Net cash, cash equivalents and restricted cash used in operating activities was $13.0 million in 2019, primarily reflecting our net loss, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by depreciation and amortization expenses of $3.7 million and operating working capital adjustments was primarily driven by increases in accounts receivable of $4.3 million due to the timing of the reimbursement of costs incurred related to our grant contract with BARDA.

Net cash, cash equivalents and restricted cash used in operating activities was $37.8 million for the six months ended June 30, 2021, primarily reflecting our net income of $32.8 million, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by the change in fair value of the Convertible Notes of $23.3 million and depreciation and amortization expenses of $14.5 million. The timing of our revenue and collections increased our accounts receivable. The expected increase in demand for our products drove the increase in inventory and prepaid expenses and other assets. The increase in deferred revenue recognized is due to the increase in product deliveries to the U.S. government.

Net cash, cash equivalents and restricted cash used in operating activities was $21.0 million for the six months ended June 30, 2020, primarily reflecting our net loss, net of non-cash cost items and changes in operating working capital. Non-cash cost adjustments were primarily driven by depreciation and amortization expenses and operating working capital adjustments was primarily driven by increases in accounts receivable and prepaid expenses and other current assets.

Cash Flows Used in Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $78.1 million in 2020, primary reflecting purchases of property and equipment to expand our production capabilities of our COVID-19 Test Kits in relation to the U.S. DoD agreement.

Net cash, cash equivalents and restricted cash used in investing activities was $2.9 million in 2019, reflecting purchases of property and equipment.

Net cash, cash equivalents and restricted cash used in investing activities was $58.9 million for the six months ended June 30, 2021, reflecting purchases of property and equipment to expand our production capabilities of our COVID-19 Test Kits in relation to the U.S. DoD agreement.

Net cash, cash equivalents and restricted cash used in investing activities was $1.3 million for the six months ended June 30, 2020, reflecting purchases of property and equipment.

Cash Flows Provided by Financing Activities

Net cash, cash equivalents and restricted cash provided by financing activities was $100.2 million in 2020, primarily reflecting proceeds received from our issuance of Series C redeemable convertible preferred stock in June 2020.

Net cash, cash equivalents and restricted cash provided by financing activities was $3.6 million in 2019, primarily reflecting proceeds from our prior loan agreement with Comerica Bank. See Note 9 to our audited financial statements included elsewhere in this prospectus.

Net cash, cash equivalents and restricted cash provided by financing activities was $219.8 million for the six months ended June 30, 2021, primarily reflecting proceeds received from our Convertible Notes issued in May 2021, partially offset by the proceeds and subsequent repayment of our Revolving Credit Agreement in May 2021. See Notes 9 and 10 to our unaudited condensed interim financial statements included elsewhere in this prospectus.

Net cash, cash equivalents and restricted cash used in financing activities was $101.7 million for the six months ended June 30, 2020, primarily reflecting proceeds received from our issuance of Series C redeemable convertible preferred stock in June 2020.

Commitments and Contingencies

See Note 16 to our unaudited interim condensed financial statements included elsewhere in this prospectus for a summary of our commitments as of June 30, 2021. In addition to the aforementioned debt obligations, our material cash commitments as of June 30, 2021 related to finance leases of manufacturing equipment totaling $3.0 million, real estate leases under non-cancelable operating lease agreements that expire at various dates through 2031 in the amount of $65.2 million, and a legal settlement of a contract dispute totaling $9.0 million, of which $6.8 million has not been paid. We expect to fund these commitments using our existing cash on hand.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based upon our financial statements included elsewhere in this prospectus, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities, as well as the reported income generated, and expenses incurred during the reporting periods. We base these estimates and judgments on historical experience, the current economic environment and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ materially from these estimates and judgments.

We believe the following accounting policies and estimates are most critical to an understanding of our financial statements. Policies and estimates are considered to be critical if they meet both of the following criteria: (i) involve a significant level of estimation uncertainty, and (ii) have had or are reasonably likely to have a material impact on our financial condition or results of operations. For a detailed discussion on the application of these and other accounting policies and estimates, refer to Note 2 to our financial statements included elsewhere in this prospectus.

Deferred Revenue Recognition

We recorded the U.S. DoD Advance as deferred revenue and recognize this liability upon satisfaction of our performance obligations to the U.S. DoD by reference to estimated future performance obligations of a follow-on agreement with the U.S. DoD and the related expected contract consideration. Changes in the assumptions used in our estimate of the future contract with the U.S. DoD, including the future pricing and the projected term of the contract and quantities purchased, may have a material impact on the timing of recognition of deferred revenue.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or an asset group may not be recoverable. If such triggering event is determined to have occurred, the asset's or asset group's carrying value is compared to the future undiscounted cash flows expected to be generated. If the carrying value exceeds the undiscounted cash flows of the asset, then an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value.

These analyses require management to make judgments and estimates about future revenue, expenses, market conditions and discount rates related to these assets. Management's assessment of whether or not a triggering event has occurred is an area of significant judgment. Additionally, if actual results are not consistent with management's estimates and assumptions, the carrying value of our long-lived assets may be overstated and a charge would need to be taken against net earnings which would adversely affect our financial statements. There were no impairment indicators during, and no impairments were recorded for the years ended December 31, 2020, and 2019.

Deferred Tax Assets (and Related Valuation Allowance)

We recognize net deferred tax assets to the extent that we believe these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that deferred tax assets may be able to be recognized in the future in excess of their net recorded amount, the deferred tax asset valuation allowance would be adjusted, which would reduce the provision for income taxes. We record uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

This requires management to make judgments and estimates regarding: (i) the timing and amount of the reversal of taxable temporary differences; (ii) expected future taxable income; and (iii) the impact of tax planning strategies. Future changes to tax rates would also impact the amounts of deferred tax assets and liabilities and could adversely affect our financial statements. All of our deferred tax assets as of December 31, 2020, were fully offset by a valuation allowance.

As of June 30, 2021, we continue to maintain a full valuation allowance on the remaining net deferred tax asset until there is sufficient evidence to support the reversal of all or an additional portion of the allowance. However, given anticipated future earnings and anticipated deferred tax liabilities, we believe that there is a reasonable possibility that by December 31, 2021, sufficient positive evidence may become available to allow us to reach a conclusion that a significant portion of the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period the release is recorded. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that we are able to actually achieve.

Stock-Based Compensation

We measure stock-based compensation expense for stock options granted to our employees and directors on the date of grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally three to four years. Our stock-based payments include stock options. Stock-based compensation expense is recognized over the requisite service period, which is generally the vesting period, on a straight-line basis. Forfeitures are recorded as they occur.

We estimate the fair value of stock options granted to our employees and directors on the grant date, and the resulting stock-based compensation expense, using the Black-Scholes-Merton, or BSM, option pricing model. The BSM option-pricing model requires the use of subjective assumptions which determine the fair value of stock option awards. These assumptions include:

- *Fair Value of Common Stock*. See the subsection titled "Common Stock Valuations" below.
- *Expected Term*. The expected term of options represents the period of time that options are expected to be outstanding. Our historical stock option exercise experience does not provide a reasonable basis upon which to estimate an expected term due to lack of sufficient data. We estimate the expected term by using the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of the options.
- *Expected Volatility*. As there has been no public market for our common stock to date, and as a result we do not have any trading history of our common stock, expected volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty.

- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.
- *Expected Dividend Yield*. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected terms, expected volatility, risk-free interest rates and expected dividend yields utilized for our stock-based compensation calculations on a prospective basis. Assumptions we used in applying the BSM option pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

See Note 13 to our audited financial statements and to our unaudited interim condensed financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the BSM option pricing model to determine the estimated fair value of our stock options.

We recorded stock-based compensation expense of $5.6 million for the six months ended June 30, 2021. As of June 30, 2021, there was $12.0 million of unamortized compensation cost. Stock-based compensation expense was $3.2 million for the year ended December 31, 2020. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, we expect our stock-based compensation expense recognized in future periods will likely significantly increase.

The intrinsic value of all outstanding options as of June 30, 2021 was $110.1 million based on the difference between the initial public offering price of $16.00 per share, and the weighted-average exercise price of outstanding options of $4.93 per share, of which approximately $85.3 million was related to vested options and approximately $24.8 million was related to unvested options.

Common Stock Valuations

As there has been no public market for our common stock to date, the estimated fair value of the common stock underlying our stock options was determined by our board of directors, with input from management. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. Our board of directors considered, among other things, valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, our board of directors considered the following methods:

- *Current Value Method*. Under the Current Value Method, our value is determined based on our balance sheet. This value is then first allocated based on the liquidation preference associated with redeemable convertible preferred stock issued as of the valuation date, and then any residual value is assigned to the common stock.
- *Option-Pricing Method*. Under the option-pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method*. The probability-weighted expected return method, or PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Historically, based on our early stage of development and other relevant factors, in accordance with the Practice Aid, we determined that an OPM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock.

Starting in December 2020, we determined that a hybrid approach utilizing the OPM and PWERM models was the most appropriate method for determining the estimated fair value our common stock. This approach involves the

estimation of the value of our company using multiple future potential outcomes and estimates the probability of each outcome. The estimated fair value of our common stock is based upon probability-weighted per share values resulting from the various future scenarios, which included a merger with a publicly traded entity and continued operation as a private company.

In addition, we also considered any secondary transactions involving our capital stock. In our evaluation of such transactions, we considered the facts and circumstances of each such transaction to determine the extent to which they represented a fair value exchange. Factors considered include transaction volume, timing, whether such transactions occurred among willing and unrelated parties, and whether such transactions involved investors with access to our financial information.

After the equity value is determined and allocated to the various classes of shares, a discount for lack of marketability, or DLOM, is applied to arrive at the fair value of the common stock. A DLOM is meant to account for the lack of marketability of a stock that is not traded on public exchanges. For financial reporting purposes, we considered the amount of time between the valuation date and the grant date of our stock options to determine whether to use the latest common stock valuation or a straight-line interpolation between the two valuation dates. This determination included an evaluation of whether the subsequent valuation indicated that any significant change in valuation had occurred between the previous valuation and the grant date.

The assumptions we use in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors with input from management exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- contemporaneous independent valuations performed by an independent third-party valuation firm;
- the prices at which we sold shares of redeemable convertible preferred stock and the superior rights and preferences of the redeemable convertible preferred stock relative to our common stock at the time of each grant;
- our stage of development and commercialization and our business strategy;
- our actual operating and financial performance;
- our current business conditions and projections;
- external market conditions affecting the diagnostics industry and trends within the diagnostics industry;
- the lack of an active public market for our common stock; and
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions.

The assumptions underlying these valuations represented our board of directors and management develop best estimates based on application of these approaches and the assumptions underlying these valuations, giving careful consideration to the advice from our third-party valuation expert. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different. Following the closing of this offering, our board of directors will determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Convertible Notes

We elected to account for the Convertible Notes issued in May 2021 using the fair value option. Such instruments are recognized at estimated fair value, with changes in estimated fair value recorded as a component of earnings in the statements of operations unless the change is a result of a change in credit risk, in which case such change in estimated fair value is recorded within other comprehensive income. Direct issuance costs are expensed as incurred and are included in interest expense in the statements of operations.

Increases or decreases in the fair value of the convertible notes can result from updates to assumptions such as the expected timing or probability of a qualified financing event, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

Product Warranty Reserve

We provide our customers with the right to receive a replacement of defective or nonconforming Cue Readers for a period of up to twelve months from the date of shipment. Although no explicit warranty is provided for Cue Cartridges, we may replace Cue Cartridges that result in invalid test results. Provisions for estimated expenses related to product warranty are made at the time products are sold. These estimates are determined using historical information that include testing failure rates, the frequency and probability of replacement units being requested, and the overall cost of replacement units. We evaluate the reserve quarterly and make adjustments when appropriate. Changes to testing failure rates, the overall cost of replacement units and replacement rates could have a material impact on our estimated liability. At December 31, 2020, and June 30, 2021, the product warranty reserve was $0 and $4.5 million, respectively.

Recently Adopted and Issued Accounting Pronouncements

Recently issued and adopted accounting pronouncements are described in Note 2 to our financial statements included elsewhere in this prospectus.

Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. In connection with the audits of our 2019 and 2020 annual financial statements, we identified material weaknesses in internal controls pertaining to information technology general controls, a lack of segregation of duties, documentation and design of formalized processes and procedures, insufficient complement of qualified resources with an appropriate level of knowledge, experience and training important to our financial reporting requirements, timely reconciliation and analysis of certain key accounts and the review of journal entries. These material weaknesses could result in material misstatements of our financial statement account balances or disclosures of our annual or interim financial statements that would not be prevented or detected. We have concluded that these material weaknesses in our internal controls over financial reporting occurred because, prior to this offering, we were a private company and did not have the internal controls necessary to satisfy the accounting and financial reporting requirements of a public company.

We began to take steps to address our material weaknesses through our remediation plan, which included the hiring of advisors in the fourth quarter of 2020, the hiring of a Chief Financial Officer in the first quarter of 2021 and the hiring of a Chief Accounting Officer and a Vice President and Treasurer in the second quarter of 2021, and the continued engagement of additional external advisors to provide financial accounting assistance in the short term. We have hired and are in the process of hiring additional personnel to improve the segregation of duties in our financial closing and reporting process and timely review of key accounts and journal entries. In addition, we have engaged external advisors to evaluate and document the design and operating effectiveness of our internal controls and assist with the remediation and implementation of our internal controls as required. We are evaluating the longer-term resource needs of our various financial functions and plan to significantly expand the size of the financial organization to help address these weaknesses.

We and our independent registered public accounting firm were not required to, and did not, perform an evaluation of our internal controls over financial reporting as of December 31, 2020, or any prior period in accordance with the provisions of the Sarbanes-Oxley Act. Accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal controls over financial reporting as required under Section 404 of the Sarbanes-Oxley Act after the completion of this offering.

Emerging Growth Company Status

We are an “emerging growth company” (as defined in the JOBS Act). Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected to use this extended transition period under the JOBS

Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies who have adopted new or revised accounting pronouncements.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. To date, we have not been exposed to material risks related to market instruments in the ordinary course of our business, but we may in the future.

Interest Rate Risk

As of June 30, 2021, we had cash, cash equivalents and restricted cash of $252.3 million. The goals of our investment policy are liquidity and capital preservation and we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States and our expenses and payment obligations are denominated in and have been satisfied with U.S. dollars. There was no foreign currency risk for the six months ended June 30, 2021. In the future, our sales may be denominated in foreign currencies and to the extent they are, we will be subject to foreign currency transaction gains or losses. To date, we have had no foreign currency transaction gains and losses, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would not have a material effect on our financial statements included elsewhere in this prospectus.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research, manufacturing and development costs. We believe that inflation has not had a material effect on our financial statements included elsewhere in this prospectus.

LETTER FROM OUR CO-FOUNDERS

Empowering Individuals to Live Healthier Lives

It all starts with the individual. Empower a person to get more information about their health and you can change the world. We founded Cue on this belief over a decade ago.

We started with first principles. In order to live their healthiest lives, people need health data that is accessible, actionable and available when and where they need. We believe we are leading a digital transformation revolution to address this, starting with diagnostics—the one area of healthcare that shapes the clinical decisions and courses of care for millions of patients.

We are building a new healthcare model—one that is designed to be convenient, connected and consumer-centric. We plan to enable end-to-end care journeys from diagnostic tests—lab-quality tests with results delivered in minutes—anywhere and anytime—to physician consultation via telemedicine through intervention. We aim to empower people by making it incredibly simple to get information about their health.

We call this Healthcare 2.0.

Over the last 10 years, we created everything we do at Cue to deliver a great experience for consumers. From how we designed the Cue Health Monitoring System which fits in the palm of your hand, to the fully guided app, our packaging and everything in between. And we are aiming to make it accessible wherever a person is: at home, at work, or at the point-of-care. We envision that people will have access to Cue through their employers, healthcare providers, payors and—and ultimately, direct to them as consumers.

Cue's success during the COVID-19 pandemic revealed the speed and value of our distinctive platform, but even more, it showed the potential of what could be ahead: the consumer power that will come when a smarter, faster and more accessible diagnostic platform is applied all across healthcare.

We envision tests to address respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management.

It is clear that the status quo in healthcare does not work. We believe healthcare is ready for a simple, convenient and digital approach for empowering each person.

Ultimately, we believe this is how you make big change in the world—by giving people health data that is accessible, actionable and available when they need it. By starting with the individual. By remembering that healthcare is always personal.

We believe this is the coming revolution.

Cue plans to lead it. And we are only just beginning.

Ayub Khattak, *Co-Founder, President and Chief Executive Officer*

Clint Sever, *Co-Founder and Chief Product Officer*

BUSINESS

Overview

Reinventing How We Interact with Our Health.

We are a health technology company, and our mission is to enable personalized, proactive and informed healthcare that empowers people to live their healthiest lives. Digital transformation has revolutionized nearly every industry except healthcare to create new, consumer-first experiences that are both personalized and empowering. We seek to usher in a new era in healthcare, what we call Healthcare 2.0, to transform how acute and chronic conditions are diagnosed and managed.

We believe the current healthcare system is challenged. Care delivery can often be uncontextualized and disconnected in an increasingly personalized and connected world. The vast majority of healthcare delivery still relies on in-person encounters at centralized locations while consumers and caregivers may often be forced to make important health decisions without complete or real-time information. The first step in many healthcare journeys is often diagnosis, a critical part of the healthcare value chain. Despite being a key basis for care decisions, we believe current diagnostic solutions are suboptimal because they are not timely, convenient, or connected to care delivery. The COVID-19 pandemic exposed the shortcomings of our healthcare system and of diagnostics in particular. A centralized and rigid testing infrastructure, the reliance on in-person encounters, and the lack of timely information illustrate how current diagnostic solutions are not built for modern care delivery to hundreds of millions of people. We believe consumers want the same tech-enabled convenient, connected, and customized experiences that have transformed their daily lives to transform their care journeys.

We are now witnessing what we believe is the beginning of a transformational shift as consumers take control of their own health. In industry after industry, disruptors are using technology to transform the consumer experience. From the way we consume content to the way we travel, we believe consumers and organizations are increasingly looking for a simple, convenient and digital first approach. We further believe that healthcare is finally ripe for a digital transformation and that it will begin with diagnostics, since approximately 70% of all clinical decisions are made utilizing diagnostic data.

We are helping pioneer this healthcare digital transformation, beginning with diagnostics. We started from consumer-centric principles and designed our proprietary platform, the Cue Integrated Care Platform, with a relentless focus on user experience, convenience, and accuracy. The Cue Integrated Care Platform consists of hardware and software components: (1) our revolutionary Cue Health Monitoring System, made up of a portable, durable and reusable reader, or Cue Reader, a single-use test cartridge, or Cue Cartridge, and a sample collection wand, or Cue Wand, (2) our Cue Data and Innovation Layer, with cloud-based data and analytics capability, (3) our Cue Virtual Care Delivery Apps, including our consumer-friendly Cue Health App and our Cue Enterprise Dashboard, and (4) our Cue Ecosystem Integrations and Apps, which allow for integrations with third-party applications and sensors.

Our platform has been designed to work seamlessly to deliver and manage health data both within the healthcare system and within the home. Through our application programming interfaces, or APIs, our platform has been engineered so that it can be directly integrated into existing workflows and on-demand services, such as telemedicine, e-prescription services, and electronic medical record, or EMR, systems. For example, we implemented an integration with one of the U.S.'s leading EMR systems on behalf of one of our customers, a leading healthcare system, to enable a seamless workflow from test ordering to test result, with our mobile app and the Cue Health Monitoring System. But beyond designing our platform to be able to integrate within the traditional healthcare system, we have built our platform to enable fast, frequent, lab-quality diagnostics by anyone, anywhere, intended to facilitate a new continuous care model of personalized and contextualized healthcare. Our first commercially available diagnostic test for use with our Cue Health Monitoring System, our COVID-19 Test Kit, which has been authorized by two Emergency Use Authorizations, or EUAs, from the U.S. Food & Drug Administration, or the FDA, for point-of-care and over-the-counter and at-home use, is an example of this. Users can run a COVID-19 test anywhere using the Cue Reader and a COVID-19 Test Kit, and have lab-quality test results delivered digitally to the user's mobile device in about 20 minutes. While our COVID-19 Test Kit is our only commercially available Test Kit and our future tests remain subject to technical development, clinical studies and regulatory authorization, clearance or approval, we have five additional Test Kits that we consider to be in late-stage technical development (influenza A/B, or flu, respiratory syncytial virus, or RSV, fertility, pregnancy, and inflammation) for which we expect to begin submitting for FDA authorization or clearance in the second half of 2022. Based on the working prototypes we have

developed for our Test Kits in late-stage technical development, as well as other Test Kits we currently have in development, and the clinical and other development work we have performed to date with respect to our Test Kits in development, we expect that all of our Test Kits currently in development will work within our Cue Health Monitoring System in a manner similar to our COVID-19 Test Kit and will be able to be utilized with our Cue Health App and the Cue Enterprise Dashboard and be capable of being integrated with existing workflows, including EMRs, and with other planned on-demand services. We believe our model, driven by our platform, will empower our users to actively manage their health, which we believe will result in improved health outcomes and a more resilient, connected, and efficient healthcare ecosystem for all. We further believe that our platform positions us to be at the center of the broader healthcare ecosystem as it continues to undergo a massive virtual and digital shift. Through our connected diagnostic solution, we seek to enable the shift of care to virtual settings, while also connecting the physical care paradigm to the new digital ecosystem.

As the COVID-19 pandemic was closing the global economy and filling hospitals in the first quarter of 2020, we rapidly focused our team on developing a COVID-19 Test Kit and did so in a matter of a few months, building on a decade of research and development on our adaptive and flexible system. Our COVID-19 test (consisting of our Cue Reader and Cue COVID-19 Test Kit) has been validated via an independent clinical study conducted by researchers at the Mayo Clinic that demonstrated our COVID-19 test has 97.8% concordance with tests performed by central labs using reverse transcription polymerase chain reaction, or RT-PCR technology, the current “gold standard” for central lab testing. Our platform has been designed to uniquely offer fast results and ease-of-use combined with the high-quality results of central lab technology, all in a device that fits in the palm of your hand.

Our first commercially available diagnostic test for use with our Cue Health Monitoring System is our COVID-19 Test Kit for ribonucleic acid, or RNA, of SARS-CoV-2, the virus that causes COVID-19. In June 2020, the U.S. Food & Drug Administration, or the FDA, granted an Emergency Use Authorization, or EUA, for our molecular COVID-19 test for point-of-care use under the supervision of qualified medical personnel. In March 2021, the FDA granted us an additional EUA for over-the-counter and at-home use of our COVID-19 test without a prescription. Our COVID-19 test is authorized for use by both symptomatic and asymptomatic individuals, and by adults and children aged two and older with adult assistance. While commercial sales of our COVID 19 Test Kit are authorized pursuant to our two EUAs, we cannot predict how long our EUAs will remain in effect and, to date, we have not obtained any clearances under Section 510(k) of the Federal Food, Drug and Cosmetic Act of 1938, as amended, or 510(k), for our COVID-19 Test Kit, which such clearance would be required to sell our COVID-19 Test Kit in the event that the FDA terminates or revokes our EUAs. In order to be eligible to receive 510(k) clearance from the FDA, we will need to conduct additional clinical studies with larger subject enrollment and more COVID-19 positive tests. We are moving forward on the additional steps we believe are required to enable us to seek 510(k) clearance, and intend to seek 510(k) clearance as soon as feasible once we have completed these steps. See “—Our First Product Offering—Cue COVID-19 Test Kit—Regulatory Status of the Cue COVID-19 Test Kit” for additional detail regarding what is required for the regulatory clearance process for our Cue COVID-19 Test Kit.

While our Cue COVID-19 Test Kit is our first, and currently only, commercially available test, our vision was always to build a broad platform that would reinvent how we interact with our health. Since our early days, we developed our platform to be able to address the majority of diagnostic tests routinely conducted in clinical laboratories because we believe that users will not only demand a simple, personalized, convenient and connected solution but also a single platform to address their healthcare needs. We are developing solutions to broaden the diagnostic use cases for our platform, such as our five tests we consider to be in late-stage technical development. Our additional planned care offerings include tests in the categories of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. We are also working to expand the functionality of our platform by adding capabilities which will enable telehealth, e-prescription and the ability to connect to third-party services to facilitate an end-to-end healthcare journey. Our focus is on creating experiences with the user at the center, enabling high satisfaction, measurable health outcomes, and more cost-effective care for the entire ecosystem.

We believe the power of our platform has been demonstrated by our substantial growth, the quality of our customers, the clinical validation of our COVID-19 Test Kit, the several regulatory authorizations we have received for our COVID-19 Test Kit, including being the first company ever to have a product authorized by the FDA for molecular-based infectious disease testing available over-the-counter for home use. Our platform was trusted by the National Basketball Association, or NBA, to help it perform COVID-19 testing in its highly publicized “Bubble” in the 2020 basketball season. Our products are used by the Mayo Clinic in their hospital network and in their

laboratories. In October 2020, we entered into a $480.9 million agreement, or the U.S. DoD agreement, with the U.S. Department of Defense, or U.S. DoD, and the U.S. Department of Health and Human Services, or U.S. HHS, to scale up our production and deliver 6,000,000 COVID-19 Test Kits and 30,000 Cue Readers. Today our platform is relied upon every day for vital COVID-19 testing across schools, enterprises, nursing homes, hospitals, physicians' offices, dental clinics, sports and other live event venues, federal and state agencies, and other settings around the country as well as by individual end-users testing in their homes. As of August 31, 2021, we had 49 active customers, which includes our largest customer by product volume to date, the U.S. DoD. We define an active customer as an entity that has entered into an agreement with us to purchase the Cue Health Monitoring System or Test Kits in the past 12 months.

Prior to March 31, 2021, we were required, pursuant to the U.S. DoD agreement, to deliver to the U.S. government all of our manufacturing output of COVID-19 Test Kits, subject to limited exceptions. The U.S. DoD agreement initially contemplated a ramp-up in of our production to 100,000 COVID-19 Test Kits per day for a seven-day period and final delivery of the required Cue Readers and Cue COVID-19 Test Kits by March 31, 2021. However, in March 2021, the production ramp up target and final product delivery dates were extended by mutual agreement to October 2021, and in September 2021, that date was extended to December 31, 2021. In April 2021, the U.S. DoD granted us a waiver whereby, effective May 1, 2021, we are permitted to sell up to 50% of our manufacturing output of Cue COVID-19 Test Kits to additional customers. Notwithstanding the waiver granted to us by the U.S. DoD, we are still required under the U.S. DoD agreement to deliver 30,000 Cue Readers, 6,000,000 COVID-19 Test Kits and 60,000 COVID-19 Control Swab Packs by December 31, 2021. As of August 31, 2021, we have delivered all of the required Cue Readers and over three and a half million COVID-19 Test Kits pursuant to the U.S. DoD agreement. We are further required to ramp up our production capacity to approximately 100,000 COVID-19 Test Kits per day for a seven-day period by December 31, 2021. As of August 31, 2021, our daily production capacity was on average over 43,000 COVID-19 Test Kits per day over a seven-day period, with a single day peak of nearly 60,000 COVID-19 Test Kits. We believe that the receipt of our waiver from the U.S. DoD will allow us to more widely commercialize our COVID-19 Test Kit. Since we received the waiver from the U.S. DoD and our second FDA EUA for over-the-counter and at-home testing for our COVID-19 Test Kit, we have been able to add several new enterprise customers and extend our business with existing customers. For example, we have added certain major technology and other enterprises as customers who are providing our solution to their employees for use in their homes as part of return to work initiatives and ongoing employee health benefits. In addition, for the 2021 and 2022 NBA basketball seasons, we have been able to extend our relationship with the NBA to provide our testing solution for use by players, their families, staff and referees, at home and on the road.

We believe our platform will allow us to develop and commercialize new tests quickly and scale rapidly, driven by our flexible technology and our in-house, vertically-integrated and automated manufacturing facilities. Our platform has the potential to perform a variety of different tests by accommodating different sample types, including saliva, blood, urine and swabs, and detecting nucleic acids, small molecules, proteins or cells. Because we developed our manufacturing facilities and processes in tandem with our technology, we were able to scale our production to produce a rate of millions of Test Kits per year using fully automated production pods. A production pod is a free standing, modular environmentally-controlled structure containing an automated test cartridge production line. Additionally, we produce our critical biochemistry in-house, including enzymes, antibodies and primers for our Cue Cartridges. As of August 31, 2021, we were manufacturing Cue Cartridges at a rate equivalent to over 15 million per year and we anticipate growing our manufacturing capacity to a rate equivalent to tens of millions of Cue Cartridges per year by the end of 2021.

We first began generating revenue from product sales in August 2020 following the receipt of our first EUA from the FDA for our COVID-19 test in June 2020. We generated approximately $201.9 million of revenue in the six months ended June 30, 2021, all of which was from product sales. Of that amount, $167.1 million, or approximately 83%, of our product revenue was from public sector entities, substantially all of which was from the U.S. DoD, with the remaining $34.8 million of product revenue generated from other customers (of which a single enterprise customer accounted for $28.9 million). We generated $23.0 million of revenue for the year ended December 31, 2020, of which approximately $15.4 million was from product sales. Of this amount, $8.9 million of product revenue was from public sector entities, substantially all of which was from the U.S. DoD, and the remaining $6.5 million of product revenue was generated from other customers. The U.S. DoD and Henry Schein accounted for approximately 80% of our product revenue in 2020. In 2019, we generated $6.6 million of revenue, none of which was from product sales. After the conclusion of the initial U.S. DoD agreement, we anticipate that the percentage of our revenue derived from non-public sector customers will increase as we continue to ramp up our manufacturing and distribution

capabilities and are able to sell more of our products to other customers, including enterprises and healthcare providers. For the six months ended June 30, 2021, our net income was $32.8 million. In 2020 and 2019, we incurred net losses of $47.4 million and $20.6 million, respectively.

Healthcare 1.0

We believe the current healthcare system suffers from centralization, and is, disconnected, analog and access-limited. We call the current system Healthcare 1.0. Globally, healthcare has become increasingly complex and we believe continues to suffer from significant fragmentation of care, while costs have continued to expand faster than the growth of the economy. Rising healthcare costs have not necessarily resulted in improved outcomes, as exemplified through the increasing prevalence of chronic conditions in the United States despite the country's approximately $4.0 trillion annual spend, the highest per capita healthcare spend in the world.

We believe Healthcare 1.0 does not meet the evolving needs of healthcare consumers who are demanding:

- control over how they manage their acute and chronic conditions as well as their overall health;
- access to actionable clinical insights;
- affordable and transparent pricing; and
- customer-centric user experiences that connect the entire care journey.

Centralized Care Limits Access

We believe healthcare that is delivered through centralized, physical locations limits access due to the inconvenience and time-consuming nature of visiting hospitals, doctors' offices, and urgent care clinics. We believe this system is also inherently rigid, siloed and disconnected when it comes to events or disruptions, such as a pandemic, where health information is not easily accessible or actionable. Centralized care also underserves remote populations and others lacking traditional access.

The Centralized Diagnostic Testing Framework Is Challenged

We believe the current centralized diagnostic ecosystem has significant shortcomings. The patient experience can be slow, costly and inefficient, yielding results that can be difficult to understand and contextualize. A patient first needs to schedule an in-person appointment with a healthcare professional, after which they often need to travel to a separate testing facility. The sample is then couriered to a lab, during which time the patient may be subject to long wait times and left unaware of the quality or status of the sample. A number of days later a result is provided through old technology that is difficult to interpret and understand. While this high latency process is unfolding, the patients underlying condition is not being addressed or contained, with the healthcare provider unable to identify the optimal treatment path required. We believe this legacy system results in underutilization of testing, healthcare professionals having to prescribe treatments without diagnostic context and a disconnected user experience that leads to suboptimal outcomes.

We believe these shortcomings impact every facet of care delivery, as brought to the forefront during the COVID-19 pandemic. In the United States today, there are hundreds of thousands of diagnostics access points to serve hundreds of millions of people. Lack of access prevents individuals and care providers from obtaining access to critical health information. The inadequate response of the healthcare system to the COVID-19 pandemic, especially when it came to simply diagnosing the disease, is a symptom of this larger problem. As of April 2020, there were only approximately 6,000 hospitals and 2,000 COVID-19 testing centers in the United States. With a daily peak of approximately 300,000 new COVID-19 cases in the United States, in 2020 the turnaround time from sample collection to receiving a COVID-19 test result in the U.S. was often measured in days or even weeks, with a typical turnaround time of approximately five days. Additionally, in April 2020, concerns of exposure to COVID-19 infection in healthcare facilities led to a breakdown of routine diagnostic screenings for other conditions, including the 90% decline in cancer screening through May 2020 and 65% decline in the number of new cancer diagnoses in April 2020. Additionally, according to U.S. HHS, nearly half of Medicare physician exams in April 2020 were conducted remotely, without access to coincident diagnostics. The lack of real-time, convenient, and readily accessible diagnostic solutions is a direct result of the legacy central lab testing model.

Legacy Infrastructure Is Not Built for Virtual Care

We believe the current centralized diagnostic and care infrastructure is even less well suited for the growing virtual care delivery model. Consumer adoption of telehealth rapidly accelerated in large part by the COVID-19 pandemic, from 11% of consumers in the United States using telehealth in 2019 to 46% percent in April 2020. As more and more people use virtual care options, the lack of connected, real-time and distributed diagnostics may become more of an issue and we believe will expose a critical weakness in the growing telehealth care delivery paradigm. For care to truly be virtual, we believe patients need the ability to obtain a diagnostic result from anywhere and at any time, rather than from a central laboratory with high latency.

Lack of Capabilities to Identify Health Threats

We believe the disconnected and high-latency diagnostic system is not able to timely deliver the information that public health agencies and healthcare providers need to identify, mitigate and monitor outbreaks of highly contagious diseases, such as COVID-19 or influenza. Without access to diagnostic data informing policymakers, providers and individuals, the containment of such outbreaks may be difficult. In addition to the issues associated with managing infection spread and population health, the lack of a decentralized and robust testing framework can also have negative collateral consequences like the capacity constraints the pandemic placed on the already strained healthcare system.

Healthcare 2.0

Digital transformation has revolutionized nearly every industry, except for healthcare, to create new, consumer-first experiences that are both personalized and empowering. We believe a new era in healthcare is beginning, Healthcare 2.0. We envision that Healthcare 2.0 will be a connected and distributed care ecosystem with seamless coordination across the physical and virtual care continuums and we believe that abundant and timely testing and real-time data will be at the center of personalized and informed care. As diagnostics-led care moves away from centralized, geographically defined settings and toward distributed, virtual modalities, we believe a connected diagnostics platform is needed to bring testing to the user, when and where they need it most.

Healthcare Is Shifting to Consumer-Focused Care and Delivery

Across multiple industries, new disruptors have used technology to transform the consumer experience. A paradigm shift is occurring in healthcare as consumers are both increasingly informed and focused on the user-experience. We believe this shift will become one of the most important factors that shapes the next decade of healthcare. As healthcare consumers pay more and more out-of-pocket, we expect they will be focused on receiving value and consumer-centric services that fit their lifestyles. New consumer driven healthcare companies and models are already rapidly growing to enable better in-person primary care experiences, telehealth and management of chronic conditions.

Diagnostics Is at the Center of Healthcare 2.0

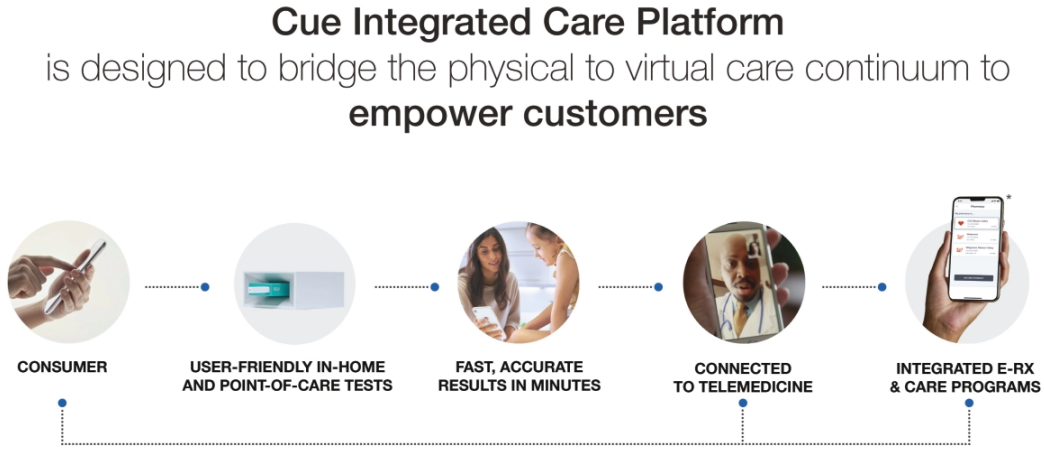
To be successful in realizing the vision of Healthcare 2.0, we need to build platforms centered around the principals of convenience, connectivity and customization that can bridge the gap between the physical and virtual care continuums. The iPhone changed the world by putting the internet in everyone’s pocket and provided a hardware-software combination that enabled an ecosystem of applications to be built on top of it. We believe diagnostic data is the key to unlocking the full potential of personalized and virtually delivered care. Without an at-home testing solution, telehealth solutions can likely still be burdened by long turnaround times, requiring individuals to visit, or mail samples to, centralized testing laboratories.

We are committed to changing the traditional diagnostic testing industry with our universal platform for enterprise, professional and personal use with broad applications. Our platform is designed to offer tangible benefits that we believe will directly address the historic challenges of and consumer dissatisfaction with the diagnostics industry.

We believe the regulatory climate is shifting in favor of decentralized diagnostics. Current leading FDA officials have been quoted as having noted the essential role that diagnostics have played in mitigating the COVID-19 pandemic. They have also stated that the lessons learned from the COVID-19 pandemic should be leveraged to drive changes of the current diagnostics system to accelerate access to accurate and reliable tests for a variety of diseases, not just COVID-19. Efforts are currently underway to increase access and facilitate point-of-care and at-home diagnostic solutions to help support public health measures and improve the overall health of the U.S. population.

We are Well Positioned to Be at the Center of Healthcare 2.0

We are focused on helping to build a new healthcare ecosystem, developed around the Cue Integrated Care Platform, that will deliver on the promise of timely, informed and connected healthcare. We are already active across a wide range of stakeholders with our COVID-19 test. We believe participants in the healthcare ecosystem will benefit from the Cue Integrated Care Platform in various ways: governments will benefit by keeping people healthy and managing population health; enterprises will benefit by maximizing employee productivity while minimizing healthcare expenses; healthcare payors and providers will benefit by evidence-based care leading to improved outcomes; and consumers will benefit from being able to take control of their healthcare journeys through more consistent diagnostic testing, leading to personalized care, faster clinical decisions, and better control of their health. We aim to make lab-quality diagnostics, such as our COVID-19 Test Kit, accompanied by real-time results, widely accessible through the use of our Cue Health Monitoring System and Cue Health App, and providing a hardware-software combination that we believe will enable healthcare stakeholders to have better outcomes.



* Depicts future product developments.

The Cue Integrated Care Platform is designed to meet the consumer wherever they are: at-home, at work, or at the point-of-care, aiming to remove the friction and inconvenience of the Healthcare 1.0 centralized diagnostic system. We believe we have the potential to become the new standard of care in diagnostics, with the ability to bridge the physical and virtual care continuums and benefit everyone by keeping people healthy and productive. Our vision is to bring diagnostics to the right point in the care journey, in any setting, enabling an end-to-end care solution. Just as monitoring combined with data-driven insights helps people with chronic conditions live healthier lives, we believe our platform will transform the way people manage their health through real-time, actionable and connected health data.

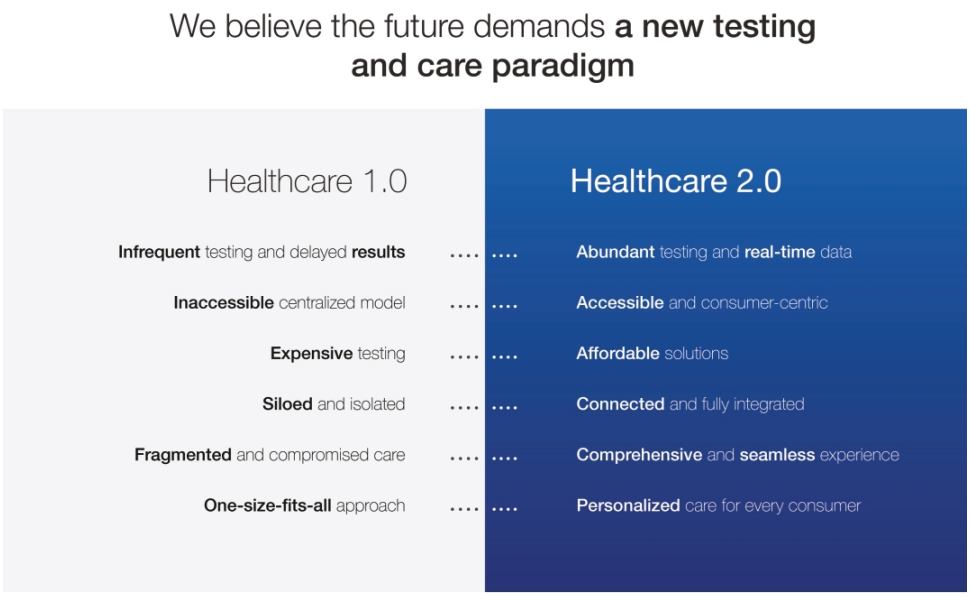
We believe the Cue Integrated Care Platform has the potential to allow consumers to reinvent the way they manage their health. There are two envisioned pathways to begin this care journey: one pathway would begin with a conversation with a doctor or telemedicine visit within the Cue Health App, wherein a doctor guides a consumer and determines a test is necessary; the second pathway would begin with a person having symptoms or knowing what they want to test for, such as COVID-19, strep throat, or flu, and there would not be a need for a telemedicine visit. We plan on giving consumers on-demand access to Cue Cartridges for a variety of different conditions by leveraging last-mile delivery infrastructure where available such as DoorDash, Amazon, goPuff, Postmates, or others. This would enable consumers to conveniently take a diagnostic test and receive results within minutes, allowing for interaction with their healthcare provider via telemedicine within the app.

A few examples could include:

- A busy parent has few good options for handling a child sick with cold and flu-like symptoms. Currently, they must take time off from work to care for the child and will often make an appointment with a pediatrician or travel to an urgent care facility. An integrated care solution with telemedicine, with diagnostics for the common respiratory threats, such as flu, COVID-19, strep throat, and RSV would allow for testing to be done conveniently and easily at-home with the guidance of a telemedicine visit if desired, and with the results delivered directly to their mobile device in minutes. Prescriptions such as Tamiflu (for influenza) or antibiotics (for strep throat) could be delivered same day to their doorstep, as the telemedicine care provider deems appropriate. Otherwise, appropriate over-the-counter medications for symptom relief could also be delivered. We believe this type of care model for respiratory diseases will become normative for this number one most common reason for a visit to urgent care in the developed world.
- A sexually active adult that wants peace of mind before or after a sexual encounter must currently make an appointment, give a sample, and typically wait days for a result on their sexual transmitted infection, or STI, status. Beyond the inconvenience, the stigma and general friction associated with getting tested is a high barrier for seeking care. We believe an integrated care solution including quick results for some of the most common STIs, consultation with a telemedicine provider through a virtual care delivery app and potential resolution with the appropriate therapy, such as an antibiotic for chlamydia delivered to them – all within hours – is an optimal flow that has the potential to become normative for handling STI related matters.

- For an individual managing a chronic condition such as cardiovascular disease, autoimmune disorder or metabolic disorder such as hypothyroidism, medication adherence and regular diagnostic testing measuring the clinically relevant biomarkers such as cholesterol are critical for effective condition management. Removing significant friction to accessing critical diagnostic information that informs disease management with doctor-informed care could provide an effective way to drive medication adherence and combined with other sensor data to form a more complete picture of health that helps drive engagement and effective disease management.

Further, we believe our platform will have wide applications in a variety of other markets, including personal health and wellness, community and public health, travel, sports and entertainment, and education. As the healthcare system undergoes the transformation to Healthcare 2.0, we believe diagnostics will be a crucial component in making virtual care a reality. Current U.S. healthcare spending on outpatient, office, and home health spend has been estimated at $1.25 trillion and the potential for virtual care was estimated at $250 billion. We believe that by introducing an integrated care solution that features advanced diagnostics, we may be able to access a significant portion of the overall virtual care market and possibly help increase the proportion of the total spend that could move to virtual care solutions.

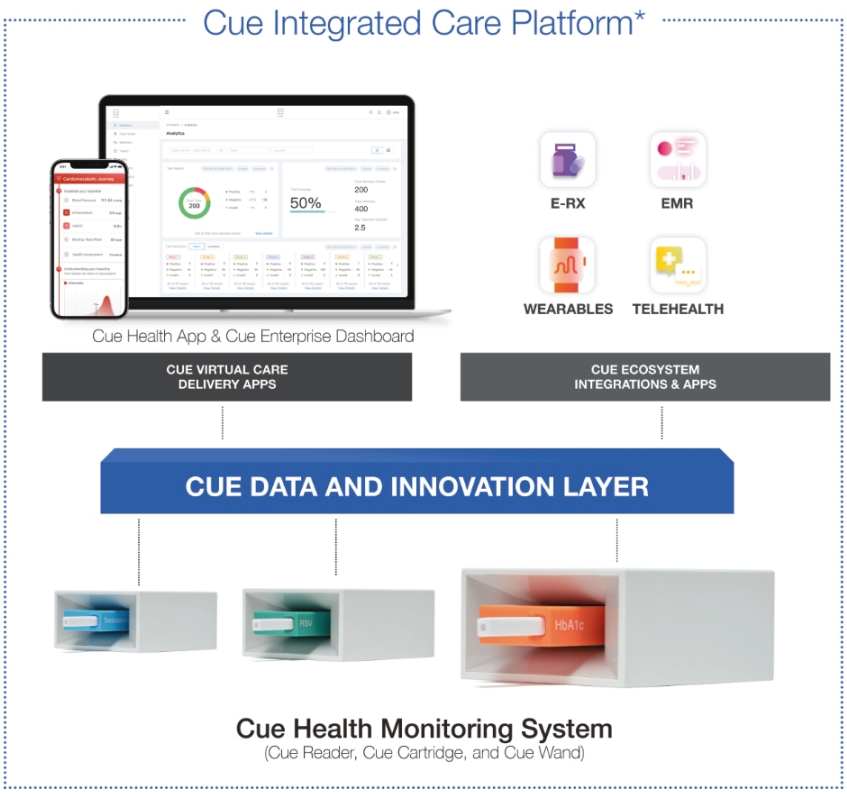


Our Solution – The Cue Integrated Care Platform

Our Cue Integrated Care Platform is simple, fast, and accurate. Our Platform is designed to harness the power of the cloud and provide consumers and enterprises with real-time access to their data and the broader healthcare ecosystem as part of our planned end-to-end solution.

Development of the Cue Integrated Care Platform is guided by our focus on the user, whether that be a clinician in a provider office or an individual at home, with a simple goal of enabling individuals and clinicians to have reliable information at their fingertips to make faster and more informed healthcare decisions. We believe we can transform disease prevention and detection globally by making important healthcare data available to anyone, anywhere, at anytime. Our system is designed to put consumers in control of their information and place diagnostic information at the center of care, where it belongs.

For consumers, we expect our platform will eliminate the friction of taking a test and communicating the results to providers. We believe increasing consumer testing at-home will lead to better outcomes. By making our platform widely available to consumers over-the-counter for use anywhere and at anytime, we aim to redefine the care workflow such that over time our platform will become the standard of care.



* Depicts future product developments.

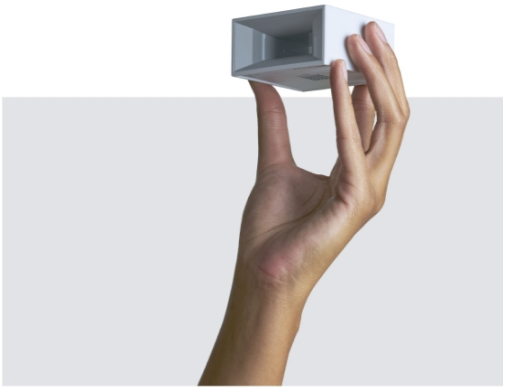
Cue Health Monitoring System

Our Cue Health Monitoring System was designed to deliver a broad menu of tests through one system, enabling two major testing modalities, nucleic acid amplification tests, or NAAT, and immunoassays, in one device. Our system is designed to handle different sample types, including saliva, blood, urine and swabs, and can detect nucleic acids, small molecules, proteins and cells. We believe this flexible design will enable us to address many of the diagnostic tests conducted in clinical laboratories, such as respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management.

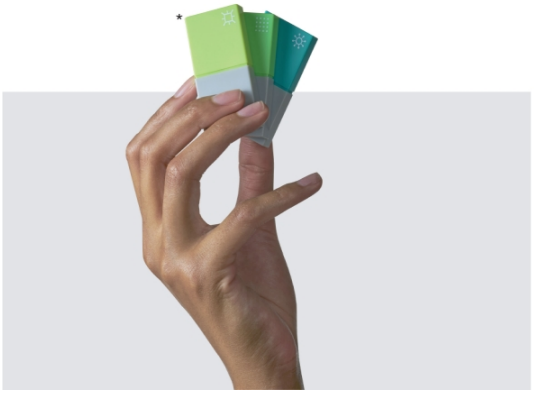
Our Cue Health Monitoring System is comprised of the following elements:

Cue Reader

The Cue Reader is an elegantly designed, automated analyzer of test results and is used with Cue Test Kits and the Cue Health App. The Cue Reader contains all the circuitry necessary to process, analyze, and communicate test results digitally, including encrypted Bluetooth radio communication and other sensors. The Cue Reader runs the Cue Cartridge and communicates the result of the test digitally via Bluetooth to the Cue Health App. The Cue Reader is easy to set-up and use and designed to be universally compatible with our current and planned future Cue Cartridges. It is a compact, battery-operated and rechargeable device that can run thousands of tests in its lifetime. The Cue Reader is portable, durable, easy-to-maintain, and has a battery life of approximately eight hours of continuous use, making it highly versatile for consumer and professional testing in a variety of settings.



Cue Test Kit: Each Cue Test Kit is comprised of a Cue Cartridge and a Cue Wand.



Cue Cartridge

Cue Cartridges are the result of significant research and development investment and we believe represent a significant advance in testing technology. Our sample-specific, single-use cartridges are designed to handle different chemistries, which allows us to create a broad menu of tests. Cue Cartridges are designed to be seamlessly inserted into the Cue Reader. Each Cue Cartridge contains the specific reagents and associated materials required to detect the target of the particular test. Cue Cartridges were designed with ease-of-use, user safety, and scalability in mind.

* Depicts future product developments.

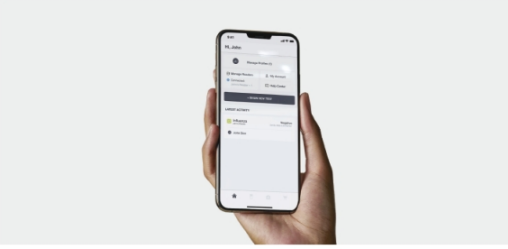
Cue Wand

Cue Wands are single-use and sterile sample collection devices that are designed to be universally compatible with the Cue Cartridges. Cue Wands are proprietary and designed only to work with the Cue Cartridges. The Cue Wand is designed to permit collection of multiple sample types, including saliva, blood, urine, and swabs, with only minor modifications. When a Cue Wand is inserted into the Cue Cartridge the system automatically runs the test and delivers the result to our Cue Health App.

Our Cue Integrated Care Platform is portable, intuitive, fast, and cloud-connected.

Portable

Compact, automated system that is battery operated and rechargeable for frequent, reliable testing in home or at point-of-care.



Intuitive

Easy to use. Fully guided experience from sample to result.

Fast & Accurate

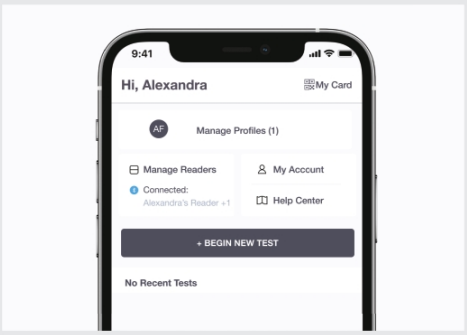
Test results in minutes. 97.8% concordance with gold-standard PCR testing as independently validated by Mayo Clinic for our Cue COVID-19 test.

Connected

Results will be able to be delivered directly to connected mobile devices enabling telemedicine, early detection, intervention, e-prescriptions, and ongoing care.

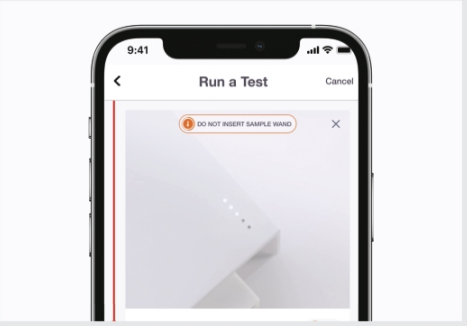
Using the Cue Health Monitoring System

The Cue Health Monitoring System is designed to be simple to set-up and use. Our COVID-19 test delivers results in approximately 20 minutes and we expect our future tests to deliver results in five to twenty-five minutes, depending on the test, and to require a user to follow only a few simple steps. The Cue Health Monitoring System was designed with a focus on the user, and our intuitive Cue Health App uses clear instructions, videos, and pictures to guide users through the entire testing process from sample collection to result, to mitigate user errors. The Cue Health Monitoring System also contains multiple safety features, including a mechanism that locks the Cue Wand inside the Cue Cartridge after insertion, and quality checks, such as confirming a Cue Cartridge is valid and has not expired. The Cue Reader in conjunction with the Cue Health App ensures that the user performs the test correctly. The Cue Health App provides instructions and informs the user of any errors detected by the Cue Reader to preclude inaccurate results. These are the key steps to operate the Cue Health Monitoring System:



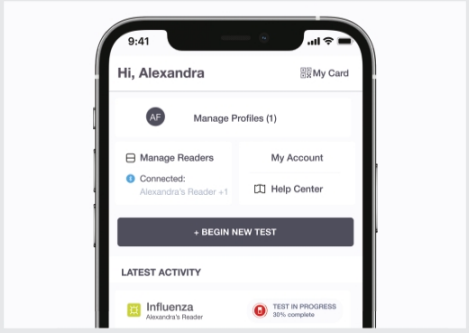
1 Open the Cue Health App and tap "+BEGIN NEW TEST," which will provide step-by-step guidance for completing the test.

2 Insert the Cue Cartridge into the Cue Reader, which initiates pre-heating and test preparation.

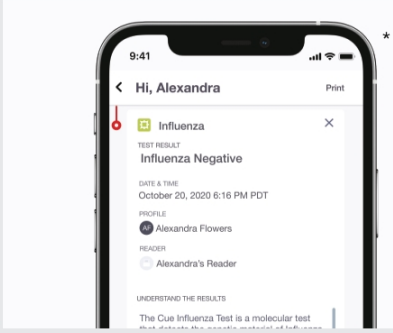


3 After approximately one minute, the Cue Health App will notify the user that the Cue Cartridge is ready to begin testing.

4 Collect the specimen using the Cue Wand and insert it into the Cartridge, which initiates the test.



5 The Cue Health App will notify the user that the test is "In Progress."



6 The Cue Health App will notify the user that the results are ready and immediately display those results on the App screen.

* Depicts future product developments.

Cue Data and Innovation Layer

Our cloud-native Cue Data and Innovation Layer stores and curates the data from our Cue Health Monitoring System and provides a secure environment for users to access current and historical health data. Our Data and Innovation Layer has the ability to collate unstructured and structured data from a wide variety of data sources, which we believe will give us the ability in the future to store and analyze more holistic sets of health data, including from other testing modalities and wearables. The Cue Integrated Care Platform was built with data security and regulatory compliance, including HIPAA, at its core.

The Cue Data and Innovation Layer provides the foundation for our Cue Virtual Care Delivery Apps and has enabled the development of our Cue Ecosystem Integrations and Apps. The Cue Data and Innovation Layer currently contains an API that allows for the data from tests performed on the Cue Health Monitoring System to be received, stored, and retrieved by the end user. For enterprises deploying the Cue Enterprise Dashboard, the Cue Data and Innovation Layer enables the creation of a network of users affiliated by roles with the enterprise. Within this network of users, the Cue Data and Innovation Layer provides the engine behind test analytics, creation of groups, scheduling and compliance, reporting, and enterprise-specific privacy policy management. The Cue Data and Innovation Layer powers the EMR integration with major EMR providers.

Cue Virtual Care Delivery Apps

Cue Health App

Our mobile app creates a secure interface between the user and their health data. For consumers, it allows a single point of entry for their health data; for healthcare professionals, it is designed to provide a unified platform for managing patient histories and, in the future, is expected to allow for telemedicine and e-prescription services. By connecting the diagnostic test results with interventions and outcomes, we believe the Cue Health App will allow users to be more engaged and satisfied with their healthcare experience, which can ultimately drive better outcomes for users. To run a Test Kit on the Cue Reader, a user will need to download and utilize the Cue Health App. As of August 31, 2021, through our 49 active customers, over 45,000 unique accounts have used the Cue Health App to run our COVID-19 Test Kit. These unique accounts include both organizations and individuals who may take tests episodically, healthcare providers running a large number of tests for multiple patients, and enterprises running a large number of tests for their entire organization, as established by the customer on a customer-by-customer basis.

Cue Enterprise Dashboard

Our dashboard is designed to allow enterprises, payors, healthcare providers and public health entities to manage population health at the organizational level and has the potential to track the efficacy of various population health programs. Accessible online, the Cue Enterprise Dashboard has the potential to help organizations manage a patient's journey from onboarding to scheduling, care management and inventory management. The Cue Enterprise Dashboard was built with a focus on user experience, simplifying the sharing of communications, such as results, records, and histories with patients and across providers and streamlining reporting requirements. Powered by our analytics engine and role-based access capabilities, it is designed to provide chief medical officers, environmental health and safety officials, and benefits managers with insight into their organization's population health, helping to facilitate efficient decision making. As of August 31, 2021, we had 60 active public sector, enterprise and provider accounts on the Cue Enterprise Dashboard. An account on the Cue Enterprise Dashboard is considered active if the customer has signed into their account and utilized the programs within the last six months. A customer may have more than one active account on the Cue Enterprise Dashboard or Data and Innovation Layer.

Cue Ecosystem Integrations and Apps

We believe that placing our API at the core of our integrated care platform will enable us to become foundational within Healthcare 2.0, powering the virtual care marketplace. By securely connecting our Cue Data and Innovation Layer with on-demand services, such as telemedicine and e-prescription services, and integrating with wearable technology, we believe we will enable a truly digital and seamless user experience. In the future, we plan on enhancing our platform to enable third-party application development and offerings that complement our solutions.

In addition, our ability to integrate with anchor EMR systems, such as Epic Systems Corporation, or Epic allows our customers to integrate our platform with their existing systems, creating an agile and responsive workflow for patient monitoring for ongoing care, better intelligence and reporting, and more efficient provider-level health management.

The Cue Virtual Care Marketplace

Our current customers can be categorized as both care consumers, enterprises and the employees that comprise them, and the care providers, doctor's offices, healthcare systems, urgent care clinics. We believe that as both care consumers and care providers take advantage of our Cue Integrated Care Platform to better diagnose and manage health, our networked Virtual Care Delivery Apps will allow us to create a marketplace where virtual care takes place, centered around objective clinical diagnostic information. We believe that the Cue Integrated Care Platform will help improve access to care while driving down healthcare costs and improving outcomes. In turn, we anticipate payors will begin to reimburse for our tests and other products offered under our Cue Integrated Care Platform. We believe that all of these dynamics will help create what we call the Cue Virtual Care Marketplace.

* Depicts future product developments.

Our Underlying Diagnostic Technology

Once a test sample is collected via the Cue Wand and inserted into the Cue Cartridge, the test automatically begins. Depending on the type of Cue Cartridge, our platform uses either a NAAT or immunoassay to perform a test. NAATs and immunoassays are two of the most common in vitro diagnostic product technologies and make up a significant portion of clinically important tests that are primarily run in centralized laboratories. For NAAT tests, primers amplify carefully selected regions within the target organism's genome. For immunoassays, antibodies conjugated to magnetic particles bind target antigens. In both cases, an internal or process control confirms proper assay execution including, as relevant, sample lysis, amplification, sample flow and assay reagent function. If the internal or process control is not detected, the test will return an invalid result. Once the assay is executed, all heating, mixing, amplification and detection takes place within the Cue Cartridge with no steps by the user. Electrodes generate a current flow to the Cue Reader which interprets a nanoampere measurement and converts it to a test result based on predetermined thresholds for qualitative tests or standard curves for quantitative tests. The Cue Reader then communicates the test result digitally, directly and wirelessly to the Cue Virtual Care Delivery Apps, which we expect will take between five and twenty-five minutes from sample collection.

Our Testing Technologies

We believe our ability to use both NAAT and immunoassays to perform tests will enable us to deliver the broadest menu of tests through our platform using our Cue Reader.

Molecular Tests

Molecular tests, also known as NAAT, target genetic material (DNA or RNA) in order to detect a broad range of infectious diseases, and are considered to be the most reliable for this purpose. PCR and isothermal amplification

are two types of molecular testing techniques. The NAAT procedure works by first making many copies of a target microbe's genetic material that is present in a specimen. This enables NAATs to detect very small amounts of DNA or RNA in a specimen, making these tests highly sensitive. In other words, NAATs can reliably detect small amounts of disease and are unlikely to return a false-negative result. The Centers for Disease Control, or CDC, has described molecular tests as the "gold standard" for clinical diagnostic detection of COVID-19. Our COVID-19 Test was the first molecular diagnostic test authorized for at-home and over-the-counter use without physician supervision or a prescription. For infectious diseases, molecular tests are more sensitive than antigen tests and have been recommended by the CDC as the preferred testing technology.

Immunoassay Tests

Immunoassays are widely used in clinical care. In clinical laboratories, the most common immunoassay technique is the is the Enzyme Linked Immunosorbent Assay, or ELISA, which is a fundamental clinical diagnostic methodology for detecting and quantifying a wide range of analytes and is one of the main modern lab techniques employed by central labs for a variety of clinical applications. Our ability to perform ELISA-like chemistry within the same cartridge structure we use to run our molecular tests enables us to detect and quantify the biomarkers necessary to expand our care offerings for use cases, including in cardiometabolic health (cholesterol, inflammation, HbA1c), men's health (testosterone, prostate specific antigen), women's health (pregnancy, fertility), other cardiac care (troponin, brain natriuretic peptide), wellness (vitamin D), and other tests.

Our Key Differentiators

We believe the following attributes differentiate us from other diagnostic solutions and digital health companies:

- ***Consumer-centric***. The Cue Integrated Care Platform is intended to revolutionize the way individuals and healthcare providers access diagnostic testing at home, at work, or at the point-of-care. Our Cue Integrated Care Platform is designed to deliver a superior user experience in any setting, one that is fully-guided, fast, accurate, and easy to use and that puts the consumer in control of their health data. Users only have to take the test and the Platform does the rest, obviating the need for many in-person testing visits and sample shipments, with a focus on at-home testing which we believe is the most consumer-centric and convenient setting. Results are presented in an easy-to-understand format through our Cue Health App and Cue Enterprise Dashboard. The digital nature of our results allows consumers to access their medical data immediately. By connecting this data to the wider healthcare ecosystem, consumers will be able to securely share their data with key stakeholders in their care journey and further streamlining the user experience. This will allow for more testing to be performed at the right point in the care journey, enabling diagnostics to drive care decisions.
- ***Lab-quality diagnostics anywhere in minutes.*** By combining the sophistication and accuracy of complex molecular testing platforms with the simplicity, convenience and speed of a consumer electronic device, our Cue Health Monitoring System has been developed to deliver highly specific and sensitive results within minutes. As a result, we believe our tests will provide a better, more convenient user experience compared to traditional lab tests while also delivering "gold standard" molecular testing results - all from a device that fits in the palm of your hand. The accuracy of the Cue Health Monitoring System was confirmed by a recent independent study, conducted by researchers at the Mayo Clinic, that found that the overall concordance between our COVID-19 test and clinical laboratory tests using NAAT was 97.8%.
- ***Extensible platform approach.*** We designed our technology, platform and infrastructure to be versatile in accommodating a wide range of tests by addressing both main analytical modalities used in diagnostic testing, immunoassays and NAAT. We believe our flexible platform will permit our planned future menu of tests to cover a large portion of diagnostic solutions typically offered by a traditional lab. The extensibility of our platform is due to the reusability of the Cue Reader, the uniform design of single-use Cue Cartridges and the synergies in chemistry across our pipeline of contemplated future tests, which we believe will allow us to quickly expand and upsell our menu in a cost-efficient manner. We have demonstrated our ability to quickly develop tests, having developed our highly accurate COVID-19 test within weeks. Our digitally native results enable seamless integration into our apps and cloud-based software platform as well as allow for integration with the broader healthcare and partner ecosystem.
- ***Vertically-integrated, automated and scalable production infrastructure.*** Our proprietary technology was designed to enable us to optimize our system across the full product life cycle from design to

manufacturing. Our integrated cartridge manufacturing and bio-production, including enzymes and chemistry, ensure the quality of our finished product. Our vertically-integrated and highly automated manufacturing facilities, which we developed alongside our science and technology and where we manufacture our Cue Cartridges, result in what we believe is a highly cost efficient and rapidly scalable manufacturing process. We further designed our manufacturing production pods to scale rapidly and allow for the production of any type of test cartridge in our planned future menu. We believe this will allow us to dramatically shorten our time to market when compared to traditional diagnostic manufacturing and to adapt to new market demands quickly and efficiently.

- ***Scaled and growing installed base.*** We have shipped over 115,000 Cue Readers across the United States as of August 31, 2021, including Cue Readers placed through our agreement with the U.S. DoD and through our other customer agreements, resulting in a broad installed base, diversified across industries, locations and end-markets such as schools, essential businesses, nursing homes, hospitals, physicians' offices, dental clinics, sports and other live events, and other settings around the country. With our EUA for at-home and over-the-counter COVID-19 testing, we expect to significantly grow our install base over the coming months and gain a place in more consumer households across the U.S. and internationally. Given our Cue Readers are reusable and universally compatible with our current and planned future Cue Cartridges, we believe this installed base and population of active users will position us well as we expand our testing menu. In addition, our installed base provides us with a wealth of data generation for our own use, and which we intend to use to improve our current and future product offerings.

Our Market Opportunity

We believe that there is substantial market opportunity for a consumer-oriented platform that sits at the nexus of healthcare and technology. We estimate that global healthcare expenditures in 2021 will reach $8.8 trillion. We estimate that the total addressable markets, or TAM, for digital health and diagnostics were approximately $120 billion and $85 billion, respectively, in 2020. Of the estimated $85 billion diagnostics market, we estimate that at-home and point-of-care testing solutions accounted for approximately $30 billion, of which, according to our internal estimates, approximately $20 billion was attributable to point-of-care testing solutions while approximately $10 billion was attributable to at-home testing solutions. We further estimate that the TAM for point-of-care diagnostics will grow to up to $51 billion by 2025. In 2021, we estimate the COVID-19 point-of-care diagnostic market alone to be at approximately $12 billion. We believe that the digital health and diagnostics markets that we are targeting are not only capable of being quickly disrupted by our Cue Integrated Care Platform, but that our TAM will continue to expand as individuals increasingly seek convenience and accessibility in their healthcare services, as awareness of our brand and platform offering grows, and as we build out our planned integrated service offering, including telehealth and e-prescription capabilities. Additionally, we believe healthcare providers and payors will continue to look for creative solutions to optimize care and cost efficiency, while employers will aim to maintain productivity and continuity.

Our Growth Strategy

Key elements of our growth strategy include:

- ***Expand our menu of tests and continue to innovate and enhance our platform.*** We plan to expand our test menu, including in the fields of respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management, with several of these tests expected to be submitted for FDA authorization or clearance by the end of 2022. Our broad planned future test menu is aimed to appeal to consumers, self-insured employers, and health plans alike and will allow for care that can be personalized to the consumer. We intend to further continue to expand our platform capabilities to provide a comprehensive user experience.
- ***Drive ecosystem adoption.*** We have been successful in our ability to integrate our platform into existing enterprise-level health management systems, allowing customers to automate workflows while allowing us to garner long-term commercial partnerships. As we enhance our Cue Integrated Care Platform, we intend to extend our integrations with leading EMR systems and to build-out additional capabilities to integrate with telemedicine and digital health providers, e-prescription, e-commerce, and other connected services, to offer consumers a frictionless, virtual-to-physical care solution that positions them for better outcomes
- ***Continue to expand our installed base and distribution network to enable pull-through of our future extended care offerings.*** We believe that the ability of customers to experience our platform for COVID-19

testing will facilitate market adoption and awareness that will benefit us as we continue to expand our test menu. We have shipped over 115,000 Cue Readers as of August 31, 2021, but we believe we are just at the beginning of our market adoption. COVID-19 has served as an accelerant for increasing the installed base of our customers, which we believe will drive natural demand to try our additional tests in development. We have significant interest from individuals, enterprises, and healthcare providers to purchase our COVID-19 test as well as interest in our future test menu. We further plan to leverage our installed base, established distribution network, and direct customer relationship through our apps to drive sales of our future test menu.

- ***Increase adoption through value-based selling and payor reimbursement.*** Our platform enables enterprise customers and payors to capture consistent, convenient and simple diagnostic information to inform key decisions. We believe this will help create positive outcomes for all stakeholders, especially our customers, as we expand our test menu. For example, helping customers test their HbA1c to manage diabetes or assess their HIV viral load to determine whether their treatment plan is effective would help payors and enterprises incur fewer costs. We believe this strategy will help accelerate our growth and drive further adoption of our platform.
- ***Continue to build the Cue brand.*** We believe that there are significant opportunities to drive increased brand awareness, educate consumers and enterprises on the benefits of diagnostics and our connected health platform, and build a lasting consumer brand. As we continue to invest in marketing, we anticipate that many customers who are not aware of our platform or the benefits of continuous, virtual care will begin using our platform. We further intend to increase our brand awareness through our partnership program. We believe the validation of leading institutions, such as the Mayo Clinic, the NBA and others, will help us to become the testing solution of choice in the enterprise and employer, travel, sports and entertainment, education, personal health and wellness, community and population health, and government market.
- ***Scale manufacturing capabilities to capitalize on demand.*** In the fall of 2020, we leased two new manufacturing facilities in an effort to scale our capabilities, and we have since commenced construction on a number of new production pods. As of August 31, 2021, we were manufacturing Cue Cartridges at a rate equivalent to over 15 million per year and we anticipate growing our manufacturing capacity to a rate equivalent to tens of millions of Cue Cartridges per year by the end of 2021.
- ***Expand our global footprint.*** We believe in the broad suitability of our platform and intend to grow our international customer base. In countries with developed healthcare systems, our value proposition is similar to that of the United States and will offer individuals, enterprises, and healthcare providers with the ability to positively impact health outcomes. In December 2020, our COVID-19 test received the CE mark, clearing it for sale and distribution in the European Union. In April 2021, we received Interim Order authorization from Health Canada to be able to sell and distribute our COVID-19 test and in August 2021 such Interim Order authorization was amended to include both point-of-care and self-testing. In countries with underdeveloped healthcare systems and infrastructure, we believe our platform will be able to provide front-line healthcare providers with access to lab-quality testing to better diagnose and treat underserved patient populations. In June 2021, our COVID-19 test received regulatory approval from the CDSCO for professional point-of-care use in India.

Our First Product Offering – Cue COVID-19 Test Kit

The Cue COVID-19 Test Kit is our first, and currently only, commercially available test. It is designed to detect SARS-CoV-2, the virus that causes COVID-19. Our COVID-19 test was the first FDA-authorized molecular diagnostic test for at-home and over-the-counter use, without physician supervision or a prescription. Internationally, we have also received the CE mark in the European Union, as well as Interim Order authorization from Health Canada, which is the department of the Government of Canada responsible for national health policy, for both professional point-of-care and self-testing, which is similar to over-the-counter authorization in the United States. In June 2021, our COVID-19 test also received regulatory approval from the Central Drugs Standard Control Organisation, India’s national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India. Our COVID-19 test provides highly accurate, lab-quality results, including for emerging variants, directly to connected mobile smart devices in about 20 minutes. A recent independent study conducted by researchers at the Mayo Clinic found that the overall concordance between our COVID-19 test and clinical laboratory tests using NAAT was 97.8%. In December 2020, our COVID-19 test was ranked by the FDA Reference Panel testing as the most sensitive among direct nasal swab point-of-care tests.

The COVID-19 Test Kit is authorized for use by both symptomatic and asymptomatic individuals, adults and children aged two and older with adult assistance. With an easy-to-use, fully guided experience, the Cue COVID-19 Test Kit offers convenience, privacy, and the ability to test frequently.

The Cue COVID-19 Test Kit runs on our Cue Reader, using our single use Cue COVID-19 Cartridge, which contains the specific reagents and associated materials required to detect the virus, and a Cue Wand.

Given our versatile platform and our team's experience in respiratory infectious disease testing, we were well-positioned to respond to the COVID-19 global pandemic. Building on our existing relationship, established in 2018, with the U.S. Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. HHS, we received funding from BARDA in March 2020 to accelerate the development, validation and FDA clearance of our COVID-19 test to help curb the spread of COVID-19. Our flexible technology and manufacturing capabilities allowed us to develop the Cue COVID-19 Test Kit in a few months. We received EUA from the FDA for point-of-care use of our COVID-19 test in June 2020 and EUA for over-the-counter and at-home use of our COVID-19 test in March 2021.

Persistence of COVID-19: The Ongoing Importance of Testing

Many prominent immunologists and infectious disease researchers have now forecasted that COVID-19 will become endemic, remaining with us for years to come. Of concern are the new COVID-19 variants which have the potential to be more transmissible, more severe, and/or have the potential to reduce the effectiveness of vaccines. On April 12, 2021, 17 months after COVID-19 was first identified, the World Health Organization, or WHO, indicated that trajectory of the coronavirus pandemic is now growing exponentially and noted that the virus is stronger and faster due to the emergence of new variants. Prior to the actual rise of new variants, the scientific consensus was that SARS-CoV-2, the virus that causes COVID-19 had a slow rate of mutation compared to other RNA-based viruses like influenza and HIV and was unlikely to have significant variation due to this slow mutation rate. As the new variants are demonstrating, this consensus was not accurate.

We believe that a number of factors and unknowns will drive the need for testing as part of an ongoing and global, multimodal approach to manage the virus into the future.

Several new COVID-19 variants are already circulating globally and within the U.S. and additional new variants are expected to occur over time. On June 8, 2021, the CDC issued an update on variants and it included five "Variants of Concern," or VOC, for which there is evidence of an increase in transmissibility, reduced efficacy of vaccination, and other factors. These VOC include: the ''Alpha Variant," fka the "U.K Variant" B.1.1.7, which is highly transmissible and might carry a higher risk of being fatal and as of May 22, 2021 was the most common source of new infections in the U.S. and Europe, is infecting more children with more young people ending up in the hospital; the "Gamma Variant," fka the "Brazil Variant" P.1, is believed to be even more transmissible than other variants, and is the second most common variant in the U.S. and has been found in over 20 countries worldwide; the "Beta Variant," fka the "South Africa Variant" B.1.351, which is highly transmissible and the "Epsilon Variant," fka the "California Variant" B.1.427 and B.1.429, which are believed to be more contagious than the original virus. The Beta Variant has been found to reduce the effectiveness of all of the major vaccines. A recent clinical trial published in the New England Journal of Medicine showed a double dose of AstraZeneca's Covid-19 vaccine was not effective in combating the Beta Variant. A study done by a team of scientists from Tel Aviv University and the Clalit healthcare organization found increased evidence that the Beta Variant was able to break through the Pfizer-BioNTech vaccine. In addition, the "Delta Variant," fka the "India Variant" B.1.617.2, first detected in India, appears to be extremely transmissible, and the first dose of a two-dose regimen is much less effective than is the first dose against other variants. Both Pfizer and AstraZeneca vaccines are only 33% effective against the Delta Variant after one dose, according to data from a U.K. study. Even countries with relatively high vaccination rates, such as the United Kingdom and United States, have seen surges in the Delta Variant. Further, doctors in Britain, Brazil, and China have reported patients becoming sicker and conditions worsening more quickly with the Delta Variant. People infected with the Delta Variant are more than twice as likely to be hospitalized for COVID-19 than those with the Alpha Variant, according to a recent study published in The Lancet Infectious Diseases Journal. The World Health Organization classifies the Delta Variant as a Variant of Concern and is believed to be the most transmissible variant so far.

While the above variants have been identified and are among the most well known, there are many other notable variants and it is not yet clear whether there already exist even more potent immune and vaccine evading variants or when or whether they will arise. The unprecedented speed of developing powerful vaccines against the variants

represents the power of advanced healthcare technology. However, the vaccines and human ingenuity face an incredibly successful and fit virus that has exhibited more highly divergent behavior than expected from the scientific community. At the beginning of the pandemic many scientists were skeptical of early anecdotes that asymptomatic spread could be a factor in spread of the SARS-CoV-2 virus until evidence mounted that this was in fact occurring. The skepticism of asymptomatic spread of COVID-19 was due to the lack of historical precedent of a virus that had significant spread driven by asymptomatic carriers. COVID-19 is a black swan event and continues to surprise scientists.

A real-world example of the impact of a variant can be seen in Manaus, Brazil, a city with 2.2 million people. Manaus, the Amazon's largest city, was highly impacted with a first wave of COVID-19 and it is estimated that 75 percent of the population was infected with the virus by October 2020. Scientists originally believed that at a 70 percent level of prior infection, a population was close if not beyond the threshold for herd immunity. However, high levels of natural immunity can also create a selection pressure that forces the virus to adapt to the immune landscape. This may explain how the new "Brazil Variant" P.1 arose in Manaus, likely in November 2020, and created a second wave of infections with a record-breaking spike in COVID-19 infections. A second wave continued throughout Brazil, and the country experienced a wave of infection from the new variant that surpassed the death rate of the first devastating wave from the original virus strain.

Despite more than a year of continuous and global COVID-19 spread, the virus is continuing to spread in parts of the world nearly unabated. The continued spread of COVID-19 provides more opportunity for the virus to accumulate mutations that confer properties that enhance its spread, especially to counter natural and vaccine based immunity. India recently reported the largest daily surge in COVID-19 infections since the pandemic began. Additionally, in Asia, cases are surging in India, the Philippines and Bangladesh and in Europe, Turkey, France and Ukraine are seeing sharp increases in infections once again. A global roll-out of vaccines is necessary to protect against severe infection, and, to date, many countries around the world haven't made progress with vaccinations. Even in highly developed countries such as the United States, the virus continues to spread regionally and in some areas like Florida, cases have risen dramatically, despite a relatively high prevalence of vaccinated individuals, estimated at greater than 50% of the U.S. population fully vaccinated. The emergence of new variants will require a global and coordinated public health effort for several years to combat and there is no guarantee that COVID-19 and its many variants will be fully suppressed into the future.

We believe it is unlikely that any vaccine will be 100% effective against COVID-19 and global health organizations and scientists are working to understand the impact of new variants on vaccine effectiveness. Even after full vaccination, research shows that there is still risk of contracting and spreading COVID-19. Furthermore, scientists believe that immunity weakens over time and that the current vaccines do not provide permanent protection from the disease thus there will be a need for booster shots over time.

We believe that achieving herd immunity is becoming increasingly unlikely. In February 2021, the CDC indicated that the U.S. is far from having herd immunity. In addition, viral infections are often seasonal and new research suggests that seasonality could be a factor in the spread of COVID-19.

As organizations across the country start to return to the office and put plans in place to return to the office, not all returning employees will be vaccinated and employers cannot mandate vaccines. There is ongoing debate about the need for vaccine disclosure in the workplace. The likely scenario is that there will be vaccinated and non-vaccinated individuals returning to the office, increasing the risk of the spread of COVID-19. In addition, immunosuppressed patients have shown to raise very minimal responses and may be susceptible to COVID-19 even after vaccination. Employers' Chief Medical Officers and EH&S leaders cannot assume that everyone has a sufficient immune response raised against the virus even if vaccinated and will continue to have to test their employees in order to create safer workplaces.

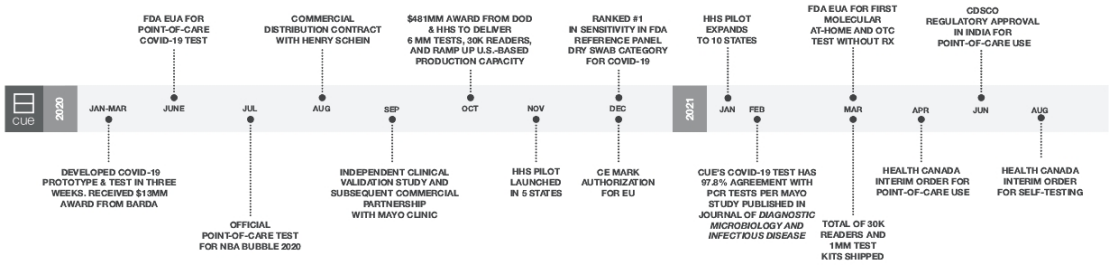
Given these factors and the number of unknowns, as well as the highly infectious nature of COVID-19, we believe that testing, along with vaccines, will be an important part of a multi-modal approach to managing COVID-19. In January 2021, the Biden Administration issued a National Strategy for the COVID-19 Response and Pandemic Preparedness plan and in it noted "To control the COVID-19 pandemic and safely reopen schools and businesses, America must have wide-spread testing." President Biden established a $50 billion plan for increased COVID-19 testing, of which $10 billion is dedicated to testing specifically to help schools re-open. Additionally, we

believe, based on various market models, that the market size for COVID-19 testing could be approximately $24 billion in 2022, $12 billion in each of 2023 and 2024, and $7 billion to $9 billion per annum thereafter. These are illustrations of how COVID-19 is expected to continue to impact the United States and how testing will be a regular part of life.

Development and Commercialization Timeline

Since the first FDA EUA authorization of the Cue COVID-19 Test in June 2020, we have been working around the clock to scale our manufacturing and focus our commercialization efforts to get as many tests as possible in the market in the midst of a pandemic. We made significant developments on regulatory authorizations, commercial activities, and manufacturing capacity.

The development and commercialization timeline for our Cue COVID-19 Test Kit is set forth below:



We continue to monitor the development and variation of SARS-CoV-2 to ensure compatibility of the COVID-19 Test Kit. Based on our own internal testing, our COVID-19 test has demonstrated a greater than 99% match for the "Alpha Variant" B.1.1.7 first detected in October 2020, the "Beta Variant" B.1.351 first detected in December 2020, the "Gamma Variant" P.1 first detected in January 2021, the "Epsilon Variant" B.1.429 first detected in July 2020 and the "Delta Variant" B.1.617.2 first detected in October 2020. As SARS-CoV-2 continues to evolve through mutation, we intend to continue to test our system to ensure our COVID-19 test delivers fast and accurate results for emerging variants.

Clinical Results

In January 2021, Mayo Clinic Laboratories published the results of an independent clinical validation study that evaluated the clinical performance of our COVID-19 test in Diagnostic Microbiology & Infection Disease, a leading peer-reviewed scientific and medical journal in the fields of clinical microbiology and the diagnosis and treatment of infectious diseases. The study was performed using lower nasal swabs and the results were compared to a reference central laboratory NAAT in 292 symptomatic and asymptomatic adults who were referred for COVID-19 testing in a community drive though collection setting operated by the Mayo Clinic. The study protocol was approved by the Mayo Clinical Institutional Review Board. The samples were collected in August 2020. Patient health status was not collected at the time of testing. The study concluded that Cue COVID-19 test was both sensitive and specific compared to central laboratory testing and that the Cue COVID-19 test for SARS-CoV-2 can be considered a feasible solution to implement at sites requiring a point-of-care solution.

The reference panel testing of 206 patients was conducted using the Hologic Aptima SARS-CoV-2 assay on a Hologic Panther instrument and the reference panel testing of 85 patients was conducted using the Mayo Clinic laboratory for testing by a RT-PCR testing on the Roche Light Cycle 480. The primary outcome was positive and negative percent agreement between the Cue COVID-19 test and the laboratory tests. The Mayo Clinic used a tie-breaker method for any sample with positive result by the laboratory test but a negative test result by the Cue COVID-19 test. If the patient had received testing by more than one reference method within 14 days of study enrollment, the tie-breaker system referred the reference result to be the result obtained by two of the three methods (Cue, Hologic Aptima and laboratory-development RT-PCR). The study did not have a method for resolving all discrepant results observed and an incorrect reference method result cannot be ruled out. It was also not possible to perform a formal limit of detection study due to the design of the assay at that time. Invalid or cancelled results were not able to be retested as directed by the instructions in the Cue COVID-19 test because study participants left the facility before point-of-care testing was completed.

The overall concordance between our COVID-19 test and the reference laboratory test was 97.8%. The positive test agreement between our COVID-19 test and the reference test was 91.7% (22/24) and 95.7% (22/23) when one patient with no tie-breaker method was excluded. The negative test agreement was 98.4% (239/243). There were 25 (8.6%) invalid or cancelled results. Since the time of the study, we have lowered the cut-off value for the internal control that detects the presence of human cellular material in the nasal sample such that 12 invalid results obtained during the study would now return a concordant negative result, and with this change there would have been 13 invalid or cancelled results.

The results of the study are presented in the table below:

	Number of samples with a reference result of		
Number of samples with a Cue result of	**Positive**	**Negative**	**Total**
Positive	22	4	26
Negative	2	239	241
Positive percent agreement	91.7%(1)	—	—
Negative percent agreement	—	98.4%	—
Total	24	243	267

(1) One discrepant positive reference sample did not have a tie-breaker method available, so positive percent agreement would be 22/23 (95.7%) excluding that sample.

The discordant results are presented in the table below.

Patient #	**Cue Result**	**Reference (method)**	**Other performed**	**Reference consensus result**
1	Negative	Positive (Hologic)	None	Positive
2	Negative	Positive (Hologic)	Negative (LTD-PCR)	Negative
3	Negative	Positive (LTD-PCR)	Positive (Hologic)	Positive
4	Positive	Negative (Hologic)	None	Negative
5	Positive	Negative (Hologic)	None	Negative
6	Positive	Negative (Hologic)	None	Negative
7	Positive	Negative (Hologic)	Negative (Hologic)	Negative

The Mayo Clinic study concluded that the Cue COVID-19 Test Kit using a lower nasal swab collection method is accurate and is both sensitive and specific compared to central laboratory testing using an NPS collection. Additionally, the study noted the Cue COVID-19 Test Kit is easy to use with minimal training or previous laboratory testing experience.

In March 2021, the FDA issued an EUA for the Cue COVID-19 Test Kit for at-home and over-the-counter use without a prescription or physician supervision, making it the first molecular diagnostic test to receive such authorization. In September 2020, the FDA required us to evaluate the analytical limit of detection and to assess the traceability of our COVID-19 test with FDA reference materials. Between December 2020 and February 2021, we conducted prospective studies at four urgent care locations and at two of our own locations to evaluate the use of the Cue COVID-19 Test Kit for at home and over-the-counter use by lay users in a simulated home use environment. Adult lay users (≥18 years of age) self-collected or collected from their child (<18 years of age) a Cue Wand nasal swab and ran the test. Adult and child subjects were enrolled in an “all comers” style at the urgent care locations. A total of 286 subjects were enrolled: 276 adults self-swabbing and self-testing to run the Cue COVID-19 Test Kit for at home and over-the-counter use and 10 children where their parent collected the nasal sample and ran the Cue COVID-19 Test Kit.

There were 38 subjects who tested positive for COVID-19, 233 subjects who tested negative for COVID-19 and 2 subjects with inconclusive results by the FDA Emergency Use Authorized molecular comparator method. Among the subjects, 10 subjects were asymptomatic positive, 123 subjects were asymptomatic negative, and 1 subject was asymptomatic inconclusive by the comparator. In this clinical study, our COVID-19 test correctly identified 96% (27/28) of positive samples from individuals known to have symptoms and correctly identified 100% (10/10) of

positive samples from individuals without symptoms. Our COVID-19 test correctly identified 99.1% (231/233) of negative samples. Additionally, in September 2020, we submitted a post-market clinical data report to the FDA as required under our EUA, which included results from the Mayo Clinic's evaluation of Cue versus an institutional reference panel.

Regulatory Status of the Cue COVID-19 Test Kit

In June 2020, the FDA granted us an EUA for our COVID-19 test for point of care use under the supervision of qualified medical personnel. In March 2021, the FDA granted us an additional EUA for over-the-counter and at-home use of our COVID-19 test without a prescription. Our COVID-19 test is authorized for use by both symptomatic and asymptomatic individuals, and by adults and children aged two and older with adult assistance. While commercial sales of our COVID-19 Test Kit are authorized pursuant to our EUA authorizations, to date we have not obtained a 510(k) clearance for our COVID-19 Test Kit, which clearance would be required in the event that the FDA terminates or revokes our EUAs. In order to be eligible to receive 510(k) clearance from the FDA, we will need to conduct additional clinical studies with larger subject enrollment and more COVID-19 positive tests.

Among other things, prior to seeking 510(k) clearance, we will need to execute a 12-day lot-to-lot precision study using three lots of Cue COVID-19 Test Cartridges. We have already drafted and are preparing to submit to the FDA a pre-submission packet of questions to seek agreement from the FDA that we do not need to repeat any of the analytical performance studies already submitted to the FDA for our EUAs. We will also need to conduct another clinical study with lay users who will self-swab and self-test. The FDA requires a larger subject enrollment and more COVID-19 positive samples for 510(k) clearance than was required for an EUA. FDA guidance has indicated that 120 samples positive for COVID-19 with at least 30 positive samples from asymptomatic individuals would potentially be sufficient for a clinical study. As part of our pre-submission packet, we intend to request that the FDA apply the samples positive for COVID-19 from the EUA lay user study we already conducted towards this “requirement” (i.e., 28 symptomatic positive samples and 10 asymptomatic positive samples). Once the study is complete, we will plan to draft the submission for 510(k) clearance for home use available over-the-counter without a prescription. With 510(k) clearance for over-the-counter and at-home use, the FDA grants automatic clearance for point-of-care, CLIA-Waived environment use.

We have an agreement with BARDA which covers the development, EUA and 510(k) clearance of our COVID- 19 Test Kit. There is approximately $5.5 million of funding remaining on this agreement to fund all of the required analytical and clinical studies necessary to complete the procedures to receive 510(k) clearance. We have also contracted with a CRO to conduct the external clinical study with lay users and the external site reproducibility study. We believe the funds from our agreement with BARDA will be sufficient to cover the required expenses, including the approximately $2.5 million CRO contract, to complete the clinical studies necessary to seek 510(k) clearance. We expect the external clinical studies to begin in the fourth quarter of 2021, with expected completion in early 2022. Assuming successful completion of these clinical studies, we intend to seek 510(k) clearance from the FDA for our COVID-19 Test Kit in the second half of 2022.

Our Go-To-Market Strategy

Our go-to-market strategy is powered by an in-house direct sales team focused on target customer segments including the public sector, healthcare providers, large enterprises, and individual consumers. Our go-to-market strategy is further complimented by our marketing team’s strategy on raising our overall brand awareness and value proposition.

Marketing

Our marketing strategy is focused on building strong brand awareness for the Cue Integrated Care Platform as a next-generation healthcare solution, with relevant, measurable value for all of our customer segments. Our marketing drives across our owned media channels (website and social networks), press releases, scientific publications, industry engagement with key stakeholders, partnerships with key opinion and market leaders, and targeted marketing through digital and non-digital channels. We anticipate investing further, using account-based marketing strategies to accelerate brand awareness and increase demand, and thus sales opportunities, across our targeted markets.

Sales

Our direct sales team engages with prospective clients and seeks to identify the best sales channel based on each client’s needs. Our go-to-market strategy is focused on allowing us access to the end user, through our Cue Integrated

Care Platform, even if the individual was acquired via our direct sales organization or through an outside sales channel. For example, if an individual obtained a Cue Health Monitoring System through their self-insured employer's COVID-19 return-to-work efforts or as a result of government-supported distribution, we can nonetheless directly engage with the end user through the Cue Health App and potentially convert them to using our planned future tests and other products we may develop. As a result, we expect that we will be able to fulfill market demand through our internal and external sales channels, while maintaining an important direct relationship for our product enhancements and care offerings.

Additionally, our relationship with U.S. DoD formed an important foundation of our initial go-to-market strategy. Our relationship with U.S. DoD helped establish our domestic manufacturing infrastructure as a critical component of ongoing national healthcare infrastructure. Our relationship with the U.S. DoD also helped commercialize the Cue Health Monitoring System as part of a critical, decentralized national diagnostic infrastructure for ongoing pandemic management. In addition, the development of Cue Readers alongside our COVID-19 Test Kits, has significantly accelerated our installed base, growth, which we believe will enable continued distribution of our COVID-19 Test Kit as well as pull-through of our planned future Cue Test Kits to key federal, state and local government agencies. Through our U.S. DoD agreement, the Cue Health Monitoring System and COVID-19 Test Kits have been deployed to over 250 school districts, nursing homes, hospitals, public health facilities and organizations, essential businesses, correctional facilities and other public sector users, as of August 15, 2021.

We expect that customer demand for our COVID-19 Test Kits will exceed our manufacturing capacity in 2021. As a result, and in light of our existing commitments under the U.S. DoD agreement and to existing customers, we are strategically selecting new customers based on the following considerations: order volume, industry diversification and potential interest in our expected future test menu.

Our direct sales team is comprised of experienced sales professionals focused on the following four categories:

- **Public Sector Sales**: Our public sector sales team identifies new opportunities within federal, state and local government agencies. While we expect that revenue from other categories of customers will become a larger component of revenue over time, our public sector sales strategy continues to look to identify opportunities with new and existing federal, state and local government agency customers.
- **Enterprise Sales**: Our enterprise sales team identifies major self-insured enterprises such as Fortune 500 companies with large-covered employee populations as well as small to medium sized businesses with healthcare plans partners and employee benefits offerings. We believe that enterprise customers will want to utilize our integrated care solutions for their employees and their families, both on-premise and at-home.
- **Healthcare Provider Sales**: Our healthcare provider sales strategy targets major healthcare systems and healthcare professionals such as hospital systems, private clinics and concierge health systems, and physicians' offices. Relationships with our customers, like our current relationship with the Mayo Clinic, help validate our platform, and we believe will help accelerate marketplace adoption of our products.
- **Direct-to-Consumer Sales**: Our direct-to-consumer sales team identifies opportunities through online and offline retail channels such as e-commerce and in-store sales.

Our customer agreements contain standard commercial terms and conditions and include payment terms, quantities, billing frequency, warranties and indemnification. Beginning in 2021, we started offering non-U.S. government customers a subscription-based purchasing option. Subscription-based customers can initially purchase a fixed number of Cue Readers at the start of the contract and commit to a fixed number of our COVID-19 Test Kits per month for the duration of the subscription agreement. We believe our subscription-based model offers customers maximum utility and allows them to reduce their purchase costs, while simultaneously creating a recurring revenue stream for us.

We believe focused efforts on each of our customer categories is critical given the unique role each plays in the healthcare ecosystem, the total size of their respective addressable markets and the potential benefits that each receive from our platform. Although our initial focus is driving adoption of our Cue Health Monitoring System and our Cue COVID-19 Test Kits, we are educating all of our current and prospective customers about the broad applicability of our Cue Integrated Care Platform and the potential roll-out of our broader test kit menu. We believe every sale of a Cue Health Monitoring System for COVID-19 testing creates a durable lasting install base for our future offerings and test kits.

Our direct go-to-market strategy is tailored to our key customer categories:

Public Sector

We have worked closely with BARDA for approximately three years, developing the Cue Health Monitoring System as a field-deployable, rapid molecular connected diagnostic technology. As a result, our first major customer agreement was in October 2020 with the U.S. HHS and the U.S. DoD. In connection with the agreement, as of August 31, 2021, we have shipped all of the Cue Readers required to be delivered by us under the U.S. DoD Agreement and over three and a half million Cue Cartridges which have been deployed to over 280 school districts, nursing homes, hospitals, public health facilities and organizations, essential businesses, correctional facilities and other public sector users. Specifically, Cue Readers and Cue Cartridges are deployed to Alaska, California, Colorado, Florida, Minnesota and Texas Departments of Public Health, among others. These represent some of the largest public health systems in the United States and play a key role in the ongoing fight against COVID-19 as well as the supervision of the overall health and wellness of large state populations. State level Department of Public Health systems guide health protocols for their respective public community clinics and public K-12 schools and as a result the Cue Health Monitoring System is in use at hundreds of K-12 schools, as well as some state sponsored community clinics. The Cue Health Monitoring System brings a valuable tool to these state level Departments of Public Health systems and other state-level end-users so they are better equipped to manage future public health needs, including those that we anticipate will be covered by our expected future test menu.

Our government sales team is currently pursuing additional agreements with the U.S. federal government as well as direct contracts with over 300 government-supplied end-users who have received the Cue Health Monitoring System as a result of our U.S. HHS and U.S. DoD deployments. We believe these end-users will have lower customer acquisition costs, with strong potential of conversion into one of our other customer categories given their experience with the platform. For example, hospitals that have received our platform are integrating the Cue Health Monitoring System into their EMRs, such as Epic, in order to seamlessly onboard, test, and deliver results to their patients. We believe these integrations, catalyzed by our COVID-19 test, will create lasting connectivity between us and our end-users and create an important foundation on which our expanded test menu can follow.

Additionally, through our agreement with the U.S. HHS and the U.S. DoD, we have deployed Cue Health Monitoring Systems to various U.S. DoD end-users. We believe our portable, accurate, intuitive and fast platform offers an especially high degree of utility for U.S. DoD applications as well as provides a new capability to bring our connected diagnostic solution to the U.S. DoD. We believe we can pursue additional direct contracts with the U.S. DoD to further support their ongoing deployments and use of the Cue Health Monitoring System.

Enterprise

Our enterprise sales team develops direct relationships with enterprises of all sizes, from small businesses to large Fortune 500 companies, across a wide variety of industries. For employers, including self-insured enterprises, we believe we provide a new ability to provide near real-time information to benefit managers and population health employees that drives decision-making, better health outcomes and ultimately cost savings at the enterprise level. We are initially supporting enterprises in their efforts to shift their large remote workforces back to in-person activities safely, by providing large-scale and real-time decentralized COVID-19 testing. Our Cue Integrated Care Platform provides a unique solution for enterprises looking to provide their employees with the ability to test themselves regularly from the comfort and convenience of their homes. Now more than ever, our enterprise customers want their employees and family units to be healthy and safe. They are seeking approved solutions that people can choose to participate in, at scale and that we believe will help save the enterprise costs over time. We form relationships with enterprises with our expected future test menu in mind and aim to partner with enterprises that will benefit from our anticipated broader test menu over time.

Healthcare Providers

We are targeting large, regional health systems with associated clinic networks as we seek to accelerate our presence in the provider segment of the market. We believe our diagnostic solution provides a unique value proposition to providers in both the acute and non-acute levels of care that has historically lacked connected platform testing and capabilities. Our healthcare sales team has already developed relationships with key healthcare providers, such as the Mayo Clinic and other leading health systems. In each of these provider systems, we have successfully integrated, or are in the process of integrating, directly into their EMR systems, such as Epic. We believe our Cue

Integrated Care Platform provides seamless use of our test kits, as patient ordering and results can happen within the healthcare provider's existing EMR workflow. Our healthcare sales team offers our integration capability when selling to this customer group.

Direct-to-Consumer

In March 2021, we received an EUA from the FDA for our COVID-19 Test Kit, allowing us to be the first molecular diagnostic test authorized for at-home and over-the-counter use. We are developing our expected future care offerings to be available in an over-the-counter setting as well, and direct-to-consumer marketing is one of our key initiatives to increase awareness of our Cue Integrated Care Platform. We are initially targeting direct-to-consumer sales through our owned sales platform, on our website and through our Cue Health App. Additionally, we are exploring direct-to-consumer sales through channel partnerships and retail distributors to further provide our platform to individuals. We anticipate selling our Cue Readers and Cue COVID-19 Test Kits individually and we may also sell through a membership model that allows consumers to have access to discounted pricing and other services, such as telemedicine, in return for annual commitments. The direct-to-customer segment may be more price sensitive than other segments, resulting in a potential negative impact to our product gross margins. We expect to launch our direct-to-consumer sales in the fourth quarter of 2021.

Strategic Collaborations and Certain Other Agreements

U.S. Government

- *BARDA* - We have partnered with BARDA since June 2018, initially focusing on a molecular influenza test using the Cue Health Monitoring System pursuant to a contract that was originally effective through January 2021 and that provided $14.0 million in base funding. In March 2020, BARDA exercised an option to accelerate development, validation and FDA clearance of our COVID-19 test for a $13.7 million award. This funding enabled us to accelerate the development and validation of our COVID-19 test. In May 2020, our original contract with BARDA was amended to increase the base value from $14.0 million to $21.8 million and to extend the contract term to January 2022. Pursuant to our agreement with BARDA, we agreed to provide regular reports to BARDA regarding our progress and certain customary oversight provisions. BARDA can terminate this agreement for convenience or if we fail to meet our obligations, subject to our opportunity to cure such defaults.
- *Department of Defense/Department of Health and Human Services*
  - In October 2020, we entered into an agreement, as amended in March 2021 and September 2021, for an aggregate of $480.9 million, with the U.S. DoD to expand our U.S.-based production capacity, to deploy 6,000,000 Cue COVID-19 Test Kits, 30,000 Cue Readers and 60,000 Cue Control Swab Packs (which is comprised of three positive and three negative control swabs per pack) pursuant to the delivery schedule under the agreement and demonstrate our ability to manufacture an average of approximately 100,000 Cue COVID-19 Cartridges per day over a consecutive seven-day period by December 31, 2021. Included as part of the $480.9 million contract amount was an upfront payment of $184.6 million to scale our manufacturing. This payment was intended to help us onshore our supply chain and rapidly increase our production capacity to enable and support domestic production of critical medical resources. As of August 31, 2021, we have shipped all of the required Cue Readers and over three and a half million COVID-19 Test Kits under the agreement.
  - In November 2020, as part of our agreement with the U.S. DoD, we started deployment of a pilot program in coordination with the U.S. HHS to assess how to best integrate our diagnostic technology into public health strategies for disease surveillance and infection control in institutions such as nursing homes. Through this program, our COVID-19 test is currently being used in the U.S. in point-of-care settings with high-concern populations and congregate care settings, such as nursing homes, long-term care, assisted living facilities, veterans' homes, K-12 schools, correctional facilities, homeless populations, essential businesses, remote and tribal communities, and hospitals. In the pilot program, U.S. HHS is using our COVID-19 test to verify antigen test results, which are less sensitive than molecular and PCR tests and occasionally prone to false positives. This pilot program was expanded to ten states in January 2021. As part of this pilot program, we have the ability to directly work with the state or local authorities that decide how to distribute our COVID-19 tests in their jurisdictions, including the ability to offer support and to sell our COVID-19 test directly to such state and local authorities.

- During the term of our agreement with the U.S. DoD, we agreed that the U.S. government would be the exclusive purchaser of our entire production until our development obligations under this agreement have been completed, except for previously existing contracts and subject to agreed upon waivers. In April 2021, we received the U.S. DoD Waiver, effective May 1, 2021, which now allows us to distribute commercially up to 50% of our COVID-19 Test production, measured monthly in arrears on a calendar month basis, to non-U.S. federal government customers and other recipients. We expect that the U.S. DoD Waiver will remain in effect for the duration of the U.S. DoD agreement; however, the U.S. government may modify the waiver upon timely written notice to reasonably accommodate changes in U.S. government requirements. We also agreed to provide regular reports as to the status of our production and distribution. We have the right to terminate this agreement without penalty if we cease to undertake development as a result of emerging safety or efficacy data, and the U.S. government can terminate the agreement if we materially fail to comply with our obligations under the agreement. If the agreement is terminated by the U.S. DoD for cause, the U.S. government may be entitled to certain remedies, including grants of licenses and penalty payments. The U.S. government may also terminate the agreement for convenience upon 30 days' notice, subject to the U.S. government retaining the right to place priority orders for up to a year following termination for other diagnostic tests manufactured using the manufacturing equipment purchased with U.S. government funds under the agreement.
- Under the agreement, following completion of our agreement, we have agreed to negotiate in good faith with the U.S. DoD for a new production agreement under which the U.S. DoD would have the right to purchase up to 45% of our quarterly production at a discount to the lowest price offered by us to a commercial customer for the same products, equivalent quantities and comparable terms of sale, subject to a price floor.

Google

In April 2021, the Company and Google LLC entered into an agreement to provide Cue Health Readers and Cue COVID-19 Test Kits to Google's U.S.-based employees through year end.

In August 2021, the Company and Google Cloud entered into a partnership to accelerate the development of a secure real-time COVID-19 variant tracking and sequencing solution. The partnership is intended to create an advanced respiratory biothreat detection system spanning from the Company's at-home diagnostic testing to full real-time viral sequencing as well as analytical and predictive capability using Google Cloud powered solutions.

Mayo Clinic

In November 2020, we established a commercial relationship with the Mayo Clinic to supply our COVID-19 Test Kits for use at the Mayo Clinic following an independent clinical validation of our COVID-19 test by the Mayo Clinic. We entered into a purchase agreement with the Mayo Clinic under which they may purchase the Cue Health Monitoring System and COVID-19 Test Kits on a purchase order basis. The purchase agreement has an initial one-year term and provides for automatic one-year renewals thereafter, unless the agreement is earlier terminated in accordance with its terms.

In April 2021, we entered into a collaboration agreement with the Mayo Clinic in which the Mayo Clinic agreed to identify us, to employers, hospitals and other U.S. clients, as a preferred partner for providing clinical diagnostic testing using our Cue Health Monitoring System, and we agreed to identify the Mayo Clinic as a preferred partner for lab and advisory services, and we jointly agreed to work together to develop go-to-market strategies for clinical diagnostic testing services. The collaboration agreement has a three-year term, unless it is earlier terminated in accordance with its terms.

NBA

In July 2020, we entered into a services agreement with the NBA to provide the Cue Health Monitoring System and our Cue COVID-19 Test Kits to the NBA to support testing within the "Bubble" established by the NBA at Disney World Resort in Orlando, Florida in order to complete the 2019–2020 NBA season, as well as community-facing testing that the NBA was engaging in as part of its operations in Orlando. We worked with the NBA to design the testing workflow, such that our test could be administered with speed, scale, and efficiency,

adhering to the NBA's health and safety protocols. Our Cue COVID-19 test was used in an assessment at high exposure points to test vendors who needed frequent access, further securing this Bubble, as part of the NBA's overall strategy, and contributing to safe, uninterrupted operations.

Under the services agreement, we agreed to supply the NBA with, among other things, tests each week through November 1, 2020, subject to preferences for essential healthcare workers, governmental entities, and certain non-profits. In November 2020, we amended our services agreement with the NBA to include a fan testing program pursuant to which we agreed to make available our COVID-19 tests to all NBA member teams in order to test certain individuals who wish to attend NBA games. Under the agreement, we were a preferred provider of COVID-19 testing for NBA members through the 2020-2021 NBA season, with our testing solution being used by players, their families and referees, at home and on the road. In September 2021, we entered into an agreement with the NBA to make available our testing solution to NBA players, staff, referees and household members as the Official Home and Point of Care Test of the NBA for the 2021-2022 NBA season.

Henry Schein

In August 2020, we entered into an exclusive distribution and supply agreement with Henry Schein, pursuant to which Henry Schein acts as our exclusive distributor in the dental market and non-exclusive distributor in other markets. Henry Schein is one of the leading distributors of products to the global dental market, with reported sales of approximately $10.1 billion in 2020. The Henry Schein agreement provides for an initial term of three years, unless earlier terminated in accordance with its terms, and provides for automatic one-year renewals thereafter, subject to either party's notice of intent not to renew.

Research and Development

Our research and development strategy focuses on developing gold-standard diagnostic science that seamlessly integrates with a connected, end-to-end digital platform. Our platform was developed over a ten-year period in our San Diego, California facilities. All of our core technology, including the chemistry, the Cue Reader and Cue Cartridge design, the Cue Health App and Cue Enterprise Dashboard is proprietary and developed in-house by us.

Our research and development team, which includes our clinical and reagent production team members, is responsible for the design, functionality and quality of our products and services. Our team is interdisciplinary in nature, including scientists, statisticians, chemists, engineers and regulatory experts. Our research and development team currently consists of 174 team members located across our facilities.

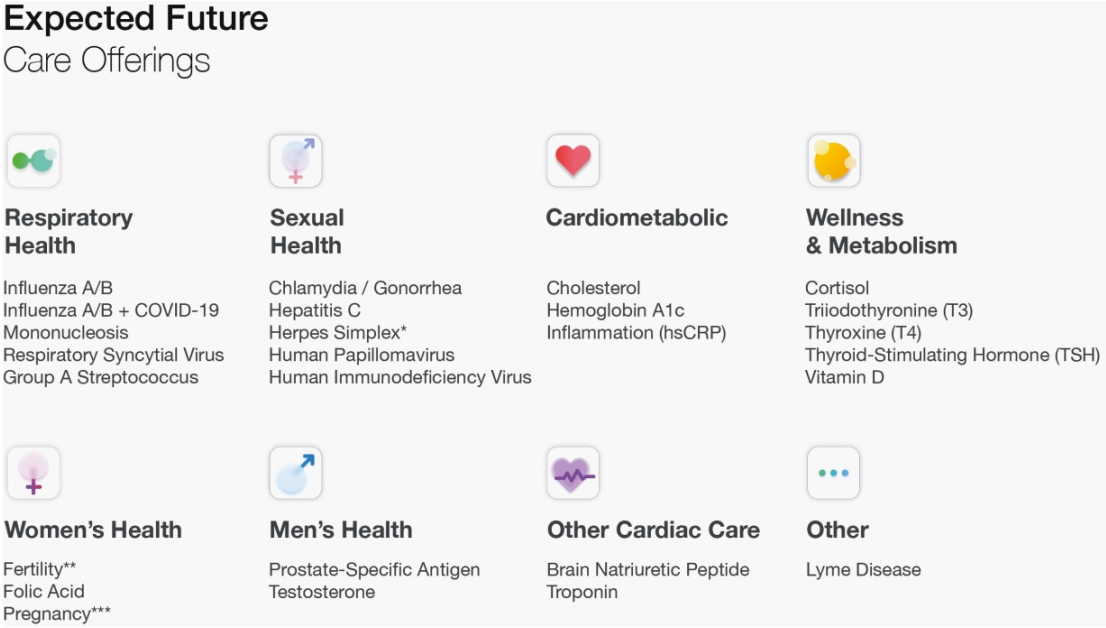
Expected Future Care Offerings

Our expected future care offerings include tests and other products across multiple categories, including respiratory health, sexual health, cardiac and metabolic health, women's health, men's health, and chronic disease management. We are currently developing both the actual diagnostic test and the accompanying software solutions in the Cue Virtual Care Delivery Apps to support our planned holistic care offerings as part of our Cue Integrated Care Platform. We expect to begin submitting additional tests for FDA authorization or clearance in the second half of 2022. Further, we intend to pursue future authorizations, clearances and approvals globally, including in the European Union, Australia, Brazil, Canada, India, Japan, within the Middle East, Singapore and the United Kingdom, and other countries. In public communications, FDA officials have indicated that they would be more amenable to approving tests for many diseases for home use as a result of lessons learned from the COVID-19 pandemic, especially testing solutions with telehealth capabilities.

We believe our expected future test menu expansion benefits from:

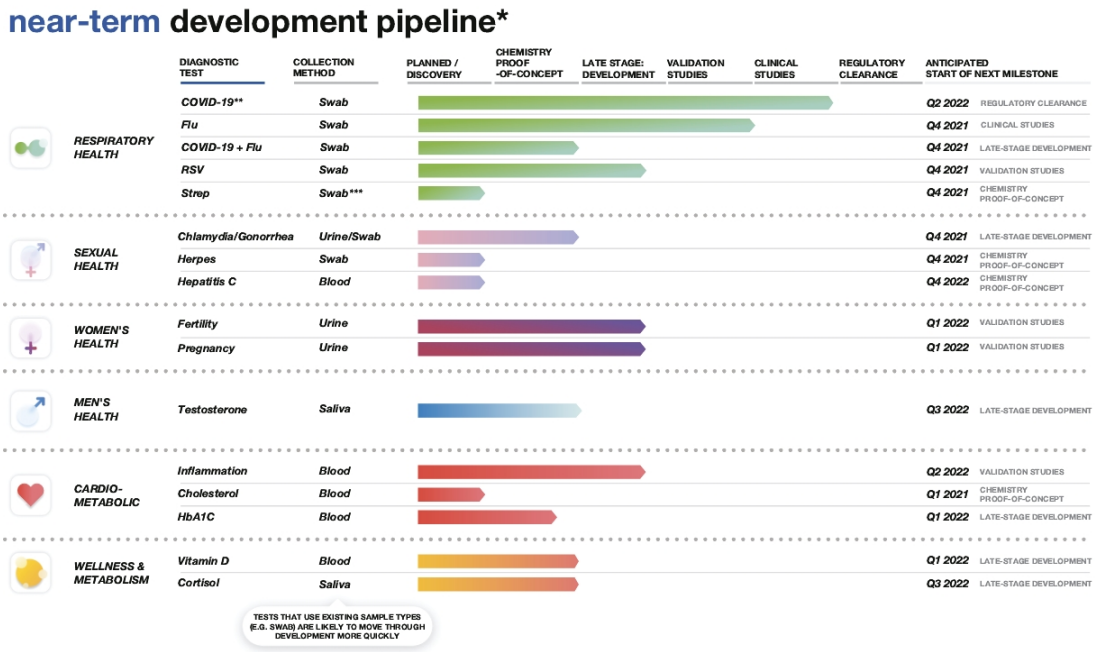
- our technical development capabilities that have led to an authorized COVID-19 test and multiple tests in late-stage technical development;
- our understanding of the regulatory pathways, including FDA authorization or clearance, for the various diagnostic tests; and
- our test-agnostic production capacity that we believe will provide us the flexibility to meet our customers' needs.

We believe our expected future care offerings will align all key healthcare stakeholders – consumers, providers, enterprises, and payors – around better health outcomes.



* HSV-1 & HSV-2
** Luteinizing Hormone (LH)
*** Human chorionic gonadotropin (hCG)

The graphic below sets forth the status of our planned future care offerings that are furthest along in development:



* This graphic does not reflect our full development pipeline but rather those of our tests that are furthest along in development.

** Our COVID-19 test has been authorized by the FDA under two EUAs. This graphic reflects progress towards 510(k) clearance. Our COVID-19 test has also received regulatory approval from the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India. Internationally, we have also received the CE mark in the European Union, as well as Interim Order authorization from Health Canada.

*** Throat swab sample may be required.

There are four phases to our product development process:

(1) Concept: The concept of the Cue Health Monitoring System, test cartridges and associated sample wands was established with the Cue Health Monitoring System and our COVID-19 Test Kit. Our planned future tests currently in development are built on the same system and concept.

(2) Development: In this phase we design and select primer pairs (in the case of a molecular test) or antibodies (in the case of an immunoassay) as part of our initial discovery process. We also develop and optimize run, wash and detection buffers as well as biosensor components. Once we have proof-of-concept for the test chemistry, we assemble cartridges with the relevant sample-input wand components and test in an iterative cycle until the system meets its design goals. At this point, when the working prototype is developed in its final form factor and is capable of running its intended sample type using the relevant sample-input wand, we consider the test to be in late-stage technical development. Once we have a final prototype we are ready to move to the qualification phase.

(3) Qualification: In this phase we initiate validation studies to execute design verification, software and firmware verification and validation, human factors studies (if needed) and analytical performance validation. The final step of the qualification phase is one or more clinical studies to determine the product's performance in the hands of end users with clinical samples.

(4) Regulatory Review: At the beginning of this phase we will collect all the data from the validation and clinical studies to draft the relevant regulatory submissions, i.e., FDA 510(k) submission or a technical file for CE-mark. During this phase, our Clinical and Regulatory teams will work closely with regulators to complete their review and obtain clearance or authorization. Once we have received authorization or clearance, this phase is complete and the product is ready to be launched and marketed.

Throughout all phases we draft and maintain the relevant design control documentation, including user needs, design inputs, verification and validation plans and protocols, design trace matrices and design outputs.

The design of our platform is such that the majority of the components, including the printed circuit board, plastics and assembly are identical among tests. Only the chemistry pellet is different between two tests that use the sample type and sample wand. For example, influenza A/B, or flu, COVID-19 and respiratory syncytial virus, or RSV, are identical tests but for the chemistry pellet. This means that the majority of the technical development for the tests in our pipeline have been completed and verified.

We currently have five tests in late-stage technical development: flu, RSV pregnancy, fertility, and inflammation. We consider a test to be in late-stage technical development when we have developed a working prototype Cue Cartridge in its final form factor, capable of running its intended sample type using its relevant Cue Wand. When a test is in late-stage technical development, we believe that all or the majority of the technical risk has been eliminated and the test performance is expected to meet regulatory and marketplace requirements. At this stage, the relevant test is ready or nearly ready for verification and validation studies. In addition to completing late-stage technical development, all of our planned tests will be required to complete validation and clinical studies. With the exception of our fertility test for over-the-counter at-home use, we generally expect that our expected future tests will then need to receive regulatory authorization, clearance or approval before they can be commercialized. Although we expect the costs associated with getting any one of our tests authorized, cleared or approved by the FDA to vary, we estimate that the clinical study costs per study for those tests requiring 510(k) clearance (which is substantially all of our expected future tests in our near-term development pipeline) range from $2.0 million to $5.0 million, with costs associated with infectious disease tests, such as flu and RSV, likely to be higher than those for other tests. In general, our tests in our near-term development pipeline will require one clinical study for clearance, though we may choose to run two clinical studies for such tests that we believe have a substantial difference in risk between obtaining clearance for over-the-counter at-home use and for use at CLIA-waived facilities. These are general estimates as it is difficult to predict with certainty how much a given test will cost to be authorized, cleared or approved by the FDA as estimated costs are subject to a number of factors, some of which are outside of our control, and are likely to vary from test to test.

The following discussion highlights indications and tests that we are focusing on for current and future development.

Respiratory

We believe respiratory diseases and illnesses exemplify the potential benefits and alignment between various stakeholders for our Cue Integrated Care Platform with its closed-loop healthcare solutions. Cold and flu-like symptoms are the number one reason for visiting an urgent care facility and result in over 100 million out-patient visits per year in the U.S. alone. In the US, the seasonal flu accounts for billions in direct medical costs per year due to urgent care visits, hospitalizations, and other treatments as well as indirect costs such as loss of productivity. These indirect costs also include the working days lost per year by those individuals who must miss work to care for themselves or a loved one.

Respiratory diseases are contagious and easily spread to others at work, the doctor’s office, schools, within the family, and other settings. Current testing solutions for the flu, strep, and other respiratory diseases require an individual to travel to a healthcare provider or lab for testing, limiting the number of people who get tested which contributes to further spread of disease. We believe access to our lab-quality testing at home combined with the context of our Cue Integrated Care Platform will result in direct and indirect savings for consumers, the healthcare system, and enterprises alike by improving health outcomes. As we continue to build out our platform, we anticipate that a user will be able to start a test, receive their test result, use telemedicine to consult with a physician about their result, order medication, and have it delivered, all from the Cue Health App. All of this could be accomplished without the user leaving their home. Employers benefit when their employees take fewer sick days and avoid spreading illness in the workplace. The healthcare providers benefit from less demand on their limited resources. Consumers benefit by catching a disease early, allowing them the opportunity to seek treatment earlier in order to feel better faster and reduce spread within their family.

Our pipeline of respiratory tests includes flu, flu + COVID-19 Multiplex, Group A Streptococcus, or strep throat, and Respiratory Syncytial Virus, or RSV, all of which are already in technical development. For those indications that already have treatments commercially available, we envision our platform providing a closed-loop, end-to-end care journey from diagnostic test to physician consultation via telemedicine and through to intervention and follow-up.

Influenza A/B

Influenza, or the flu, is an infectious respiratory disease caused by an influenza virus. The CDC estimates that influenza has been responsible for between 12,000 and 61,000 deaths in the United States annually since 2010. In the United States, seasonal influenza is estimated to result in billions of dollars of direct and indirect economic costs. According to industry estimates, a future influenza pandemic could cause hundreds of billions of dollars in direct and indirect costs. Given that the COVID-19 pandemic has caused an estimated economic cost of $16.0 trillion dollars, we expect these estimates may be low.

The Cue influenza test is in late-stage technical development. In early 2020, we had fully functioning influenza tests and associated software that had progressed through analytical validation and had begun clinical validation. We started our external influenza clinical study in January 2020. The study utilized a number of sites throughout the country. Many of these sites were research facilities that focused on clinical studies and do not provide clinical care. When the COVID-19 pandemic began spreading in the U.S. in early February and March 2020, many of these facilities began preventing potential enrollees from entering the sites if they exhibited any respiratory disease systems. This significantly impacted the enrollment of participants into our influenza test studies. We subsequently chose to pause, and ultimately stop, the study due to very low enrollment.

The year-long delay has given us an opportunity to further optimize the performance of our influenza test. We expect to resume the study in late 2021, with the goal of completing the study in the spring of 2022, followed by submission for over-the-counter 510(k) clearance. Assuming successful completion of the study, we expect we would expect to seek FDA clearance by the end of 2022, and assuming receipt of the 510(k) clearance, to be able to commercialize this test shortly thereafter. Since the sample type for the Cue influenza test will be a lower nasal swab collected using the same Cue Wand as the Cue COVID-19 Test, the sample collector wand and interface is complete and no further optimization is needed or expected.

Influenza A/B + COVID-19 Multiplex

Recent research states that SARS-CoV-2 is likely to become a reoccurring seasonal virus, similar to the flu. With the seasonal flu and COVID-19 having similar symptoms including fever, cough and fatigue, a multiplex test that can test for both viruses at the same time will be beneficial in order to differentially diagnose and appropriately treat these patients.

Technical development for the Cue Influenza A/B + COVID-19 Multiplex test is in the chemistry proof-of-concept stage of the development phase. We have substantially completed the development of the enzyme chemistry and continue to optimize the performance of the chemistry. Additional detection chemistry is also under development. We are in the process of updating the printed circuit board design of the cartridge to accommodate additional detection chemistry. The Cue Influenza A/B + COVID-19 Multiplex test will use the same Cue Wand configuration for lower nasal swab collection that our Cue COVID-19 Test uses. Given the ongoing and urgent need for COVID-19 testing, we intend to complete technical development, conduct appropriate clinical studies as needed and apply for an EUA between the end of 2021 and early 2022 for our Cue Influenza A/B + COVID-19 Multiplex test. If we are successful in obtaining an EUA, we would expect to commercialize this test shortly thereafter.

Group A Streptococcus

The incidence of Group A Streptococcus, commonly known as strep throat, is consistently high with 616 million people contracting strep, and half a million people dying due to severe strep throat, each year. Studies show that accurate and rapid diagnosis of strep throat may reduce the overuse of antibiotics. Literature shows that 37% of children visiting the doctor in 2010-2011 with sore throat tested positive for strep throat, but 56% of visits were associated with antibiotic prescriptions. Similarly, 18% of adults visiting the doctor with a sore throat tested positive for strep throat, but 72% were treated with antibiotics. Our Cue Group A Strep test, which has the potential to provide fast and accurate results at home, may improve clinical outcomes by facilitating quick diagnosis and treatment with antibiotic therapy if indicated by a physician within the integrated care offering; or, conversely, if not indicated, antibiotic resistance will be reduced by avoiding unnecessary prescriptions both for the individual and in aggregate across the human population.

Our strep test is in the planning/development, stage of development. Additionally, we are in the process of developing run buffer for bacterial lysis. Our preliminary research shows the sample type for the Cue Group A Strep test can be a buccal/tongue swab sample, but it is possible that for maximal sensitivity of detection, the test may require a throat swab.

Respiratory Syncytial Virus

RSV is one of the most common causes of childhood illness. Each year in the United States, RSV leads to approximately 2.1 million outpatient visits among children younger than 5 years old, 58,000 hospitalizations among children younger than 5 years old, and can result in death. Similar to the flu, a readily available at-home RSV test could help greatly reduce the severity and spread of RSV annually by allowing individuals to test themselves at home easily and safely when experiencing symptoms, avoiding exposure to others at work, school and in other settings.

Our RSV test is in phase 2, late-stage technical development. While we have fully functioning prototypes of the cartridges and associated testing software for RSV, we continue to optimize the RSV test with more rounds of primer design. We also continue to develop the associated software. We anticipate that collection of the sample will be with a lower nasal swab, the same method used for our COVID-19 Test. We expect to start and complete analytical performance validation in the fall of 2021 and to begin clinical studies in late 2021. We anticipate the study will be completed in the spring of 2022, followed by submission for over-the-counter 510(k) clearance. We expect to seek FDA clearance by the end of 2022 and, assuming receipt of 510(k) clearance, to be able to commercialize this test shortly thereafter.

Sexual Health

Sexual Health, as a category, provides another example of how our integrated care solution can create alignment between all key healthcare stakeholders. It is estimated that 1 in 5 people in the U.S. have a Sexually Transmitted Infection or STI. CDC speculates that the rise of dating apps and behavior changes among sexually active individuals (Dating 2.0) has led to various STDs being on the rise for the first time since 2006. STIs can have serious health consequences including infertility, liver problems, and other issues. The majority of STIs are treatable with simple interventions.

Yet, many consumers are hesitant to visit a healthcare provider office to consult or get tested for STIs, which can result in continued spread of the disease and sometimes serious health conditions for the individual due to untreated infections. We believe an accessible test that can be taken from the privacy of the home would result in more frequent and timely testing, allowing for the individual to avoid downstream negative health consequences. Additionally, in aggregate, the effect of testing could potentially drive reduced spread of these infections.

Enterprises can benefit from an integrated care solution for STIs for their employee population. While this data would not typically be shared with an enterprise, they still benefit from employees who catch an infection sooner and treat it more quickly. The more efficient diagnosis and treatment by testing earlier in an integrated care context reduces the risk of employees becoming seriously ill, resulting in fewer sick days and less associated direct medical care costs.

In addition to benefiting from lower direct medical costs associated with downstream consequences of undiagnosed and unmanaged STIs in their covered populations, payors benefit from the screening because STIs are part of the Healthcare Effectiveness Data and Information Set, or HEDIS, measure. HEDIS scores are determined by up to 81 health measures and are a tool to judge care and service performance of health plans. Ultimately, the HEDIS score is used by the CMS to determine Medicare Advantage Quality Bonus Payments – a direct impact on the health plan's bottom line. One such HEDIS measure is based on the percentage of women in the health plan 16-24 years old who are sexually active and have at least one test for chlamydia during the year. The higher the percentage, the better the HEDIS score for that health plan, resulting in higher revenue for the health plan. Therefore, the payor benefits from an accessible at-home test that encourages testing by the consumer.

Our pipeline of sexual health tests includes Chlamydia and Gonorrhea, or CT/NG, HIV, Herpes and Hepatitis C, with the following tests representing some of our near-term priorities:

Chlamydia and Gonorrhea

Chlamydia and gonorrhea, or CT/NG, are two of the most common, yet easily treatable, STIs in the United States. When left untreated, these diseases can lead to a variety of serious issues, including infertility, pelvic inflammatory disease, pregnancy complications, and increased risk of HIV acquisition. According to the CDC, in 2018, new infections of chlamydia and gonorrhea accounted for $962 million in direct medical costs alone, which does not include indirect costs (such as lost productivity and other non-medical costs). The American Congress of Obstetricians and Gynecologists recommends annual CT/NG screening of all sexually active women ages 25 and younger and of all women over the age of 25 with certain risk factors. We believe the availability of a reliable testing

option that can be performed in the privacy of the home and that provides fast results will increase testing for these STIs and which will drive immediate and increased intervention.

Our CT/NG test is in the phase 3, chemistry proof of concept, stage of development with initial bioinformatic analysis and primer design underway. Development of run buffer for bacterial lysis is underway and primer test in cartridges has started. Additional detection chemistry is also under development. The sample for this test can be either urine, collected by the Cue fluid collection wand, or a vaginal swab, taken with the Cue Wand.

Hepatitis C

Hepatitis C is a viral infection that causes liver inflammation, sometimes leading to serious liver damage. It is caused by the hepatitis C virus, or HCV, spreading through contaminated blood. The virus can cause both acute and chronic hepatitis and its severity ranges from a mild, few weeks, and more than half of people infected, it becomes a chronic illness. It is also a major cause of liver cancer.

About 50 percent of people with HCV do not know that they are infected as symptoms can take decades to appear. In fact, millions of people in the United States have hepatitis C and don't know they have the virus. Today, chronic HCV is usually curable with oral medications taken every day for two to six months. The U.S. Preventive Services Task Force recommends that all adults ages 18 to 79 years be screened for hepatitis C, even people without symptoms. We believe the availability of a reliable testing option that can be performed in the privacy of the home or easily at the point-of-care and that provides fast results will increase testing for hepatitis C, which could in turn drive immediate and increased intervention for this curable disease.

Our HCV test is in the phase 2, planning/discovery, stage of development. We plan on developing a test for HCV using the Cue blood collection wand for a fingerstick of blood and using the test cartridge to detect the presence of antibodies against HCV. Later developments could include a quantitative HCV measurement from plasma to monitor the progression and effectiveness of the therapies used to treat the individuals that have had HCV diagnosis and are undergoing antiviral therapy.

Herpes Simplex Virus

Estimates show that about half a billion people globally are living with genital herpes, and several billion have an oral herpes infection. Herpes simplex virus, or HSV, is a common and easily transmissible virus that causes lifelong viral infection. HSV-1 and HSV-2, the two known subtypes, can cause painful oral and genital infections, with HSV-2 being the major cause of genital herpes. Most people living with HSV are unaware they have the infection. Symptoms are generally mild or not present at all, which makes diagnosis difficult. HSV infections are most contagious when symptoms are present, however, the infection can be spread in the absence of symptoms. Infection with HSV-2 infections increase the risk of acquiring and transmitting HIV. After becoming infected, HSV becomes latent in nerve roots and can reactivate, resulting in symptom recurrence.

Genital herpes can lead to stigma and psychological distress and can have an important impact on quality of life and sexual and reproductive health. Preventing acquisition of a new genital herpes infection is particularly important for women in late pregnancy, as this is when the risk for neonatal herpes is greatest. Immunocompromised individuals, including those who are HIV positive and those who have undergone transplants, can be at higher risk for more severe HSV infections. We believe the availability of a reliable testing option that can be performed in the privacy of the home or easily at the point-of-care and that provides fast results will increase testing for HSV, which could in turn will drive immediate and increased intervention. Our HSV test is in the phase 2, planning/discovery, stage of development.

Human Immunodeficiency Virus

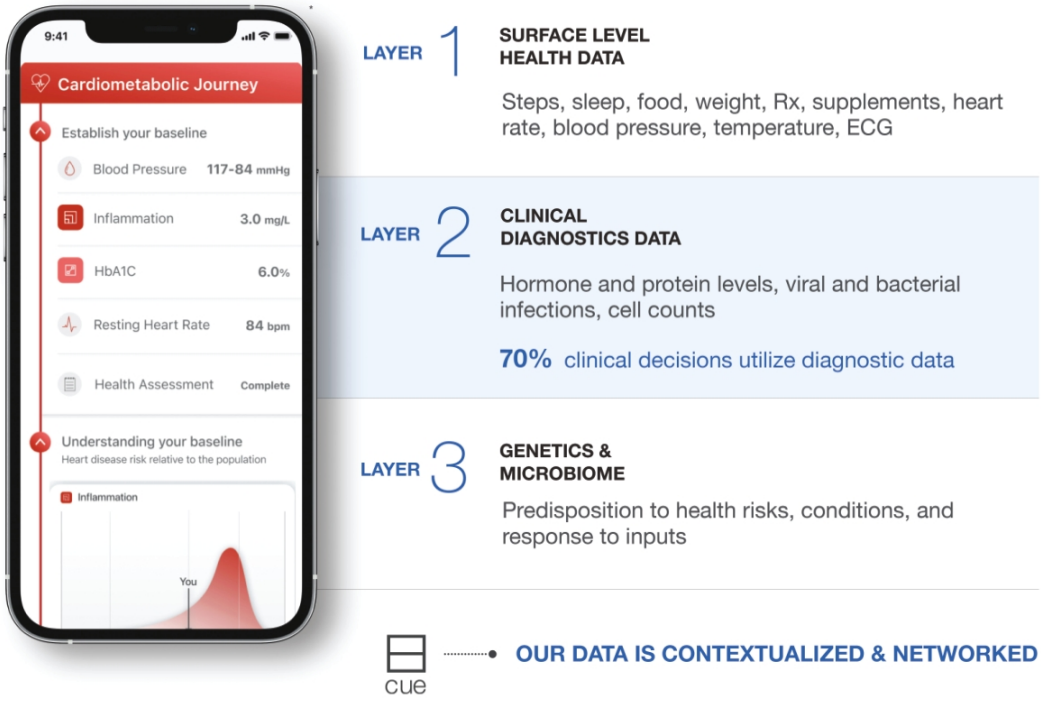
Human immunodeficiency virus, or HIV, the virus that causes acquired immunodeficiency syndrome, or AIDS, is one of the most significant global public health challenges. There are over 35 million people living with HIV, most of which are located in Sub-Saharan Africa. For individuals diagnosed with HIV, measurement of HIV viral load, or VL, in HIV-1 infected individuals is the most important indicator of response to antiretroviral therapy. However, due to logistical challenges, result mismanagement, high cost, and lack of trained personnel, implementation of VL monitoring tests has been difficult in resource limited settings. Our HIV-1 viral load monitoring test is designed to provide results at the point-of-care and improve availability of diagnostic information and better inform treatment pathways. In collaboration with Janssen Pharmaceuticals, Inc., (Janssen), we developed a cartridge to differentiate between patients with VL above and below 1,000 copies (cps)/mL from a finger prick blood sample within 20 minutes.

Our HIV viral load test is in late-stage technical development and has completed feasibility testing to detect HIV-1 samples in accordance with the intended use population. We have completed the fundamental HIV-1 chemistry development and have built multiple prototype lots of cartridges. Cartridges were tested using clinical samples and the relevant Cue fluid collection want, in the Cue Reader connected to the Cue App. The test demonstrated the ability to detect selected HIV-1 Group M subtypes, Group O and N viruses and preliminary capability to achieve analytical sensitivity. We intend to build on this technical development to pursue commercialization of a nucleic acid amplification test for HIV detection from blood or plasma samples.

Chronic Disease Management

Chronic diseases are the leading driver of the nearly $4.0 trillion dollar annual direct medical expenditures in the U.S. Chronic disease management represents one of the largest opportunities for an integrated care solution to drive improved outcomes for all stakeholders. Chronic diseases such as heart disease, diabetes, autoimmune disorders, and cancer are the leading causes of death and disability in the United States. It is estimated that six in ten adults have one chronic disease and four in ten have two or more. For individuals living with a chronic disease, ongoing disease management is required including regular in-person testing with in-person consultation with a healthcare provider. These visits are time-consuming, inefficient and we believe often leads to poor disease management because of the various friction points and lack of contextualized and connected care.

We believe the Cue Integrated Care Platform has the potential to streamline how consumers with chronic conditions access the diagnostic data they need and the associated provider consultations. By making it more convenient to measure the diagnostic information that measures the present state of a chronic condition, the platform can help drive adherence as people can see the impact more quickly of the various interventions such as medications and digital health interventions. In addition, we believe this end-to-end solution to ongoing care management can allow people to have a more comprehensive picture of one's health through Cue Ecosystem Integration and Apps from third party sensors which help monitor layers of health information including activity levels, diet, and sleep. The graphic below illustrates one example of how we anticipate that the Cue Integrated Care Platform will be able to be used for chronic disease management.

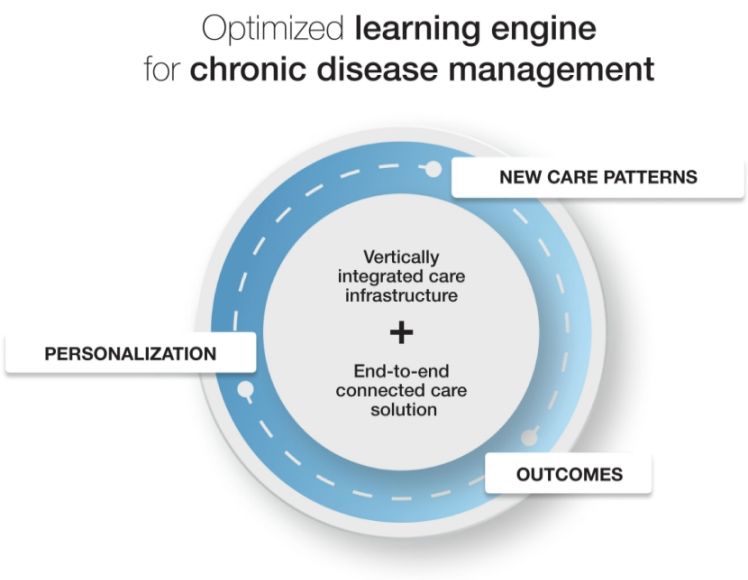


* Depicts future product developments.

Furthermore, as more health layers, such as genetic predisposition information, become available within the ecosystem of integrations, we believe chronic disease populations will be able to be subclassified in order to personalize the care patterns. Other ways to subclassifying the larger cohort of affected consumers could be to use some of the clinical biomarkers such as hsCRP in the case of heart disease to help stratify risk levels and thereby subclassify by risk level. Over time, by having the diagnostic data that actually measures the outcomes, we believe that a feedback loop to improve care can be optimized.

Key healthcare stakeholders all benefit from alleviating some of the high costs associated with chronic diseases.

Our pipeline of care offerings for chronic disease management and general health and wellness includes products for measuring cholesterol, inflammation, HbA1c, vitamin D, cortisol, and thyroid hormones. The following products represent some of our near-term priorities:



Cardiometabolic Health

Coronary heart disease is the leading cause of death in the United States. It is estimated that 47 million people in United States have cardiometabolic disorders, putting them at an increased risk of developing heart disease or type 2 diabetes. Cardiometabolic risk factors are a group of conditions that often occur together and are a major cause of heart and vascular disease and they include diabetes.

Cardiometabolic disorders represent a cluster of interrelated risk factors, primarily hypertension, elevated fasting blood sugar, dyslipidemia, abdominal obesity and elevated triglycerides. This strong association between diabetes and cardiovascular health provides a compelling reason for health care providers to work together to reduce cardiometabolic risk factors through early assessment and targeted interventions.

Our planned cardiometabolic offerings are an illustration of how consistent testing and our natively digital and connected system could benefit health plans as well as the consumer. Continuous tracking of measures like inflammation, HbA1c, and cholesterol can indicate to the consumer and their healthcare provider signs of a more serious disease, which would help prevent those other diseases. The ability to view current as well as historical diagnostic data side-by-side in a natively digital system directly connected to the healthcare provider can initiate immediate changes in behavior based on real-time data. The continuous monitoring of health indicators such as inflammation, HbA1c, and cholesterol is made easy by our convenient and connected platform and we believe will result in early detection, prevention, and control of heart disease, stroke, and other cardiovascular diseases, saving money and lives, benefiting all the key stakeholders in healthcare.

Inflammation

Heart disease, stroke, and other cardiovascular diseases cause one in three deaths in the United States. These diseases cost the U.S. healthcare system $214 billion per year and cause $138 billion in lost productivity from

premature death alone. The C-reactive protein, or CRP, is produced by the liver when inflammation is present somewhere in the body. The high sensitivity CRP, or hsCRP, test measures small amounts of CRP in the blood. Research has shown that elevated hsCRP levels can indicate heart attack and stroke risk, even in apparently healthy individuals. Elevated hsCRP levels are also a risk factor for people who do not have other risk factors that medical practitioners commonly look for such as high cholesterol or high blood pressure. For people who have had a heart attack, elevated hsCRP levels may indicate if they are at risk for another heart attack or an ischemic stroke. The periodic monitoring of hsCRP could be made easy by our convenient and connected platform and we believe will result in early detection, prevention, and control of heart disease, stroke, and other cardiovascular diseases.

The measurement of hsCRP, since it is a measure of inflammation generally, could also have significant implications in monitoring other chronic conditions that often have chronic inflammation as a unifying factor and indication of underlying disease state. These diseases include autoimmune disorders such as rheumatoid arthritis, lupus and inflammatory bowel diseases such as Crohn's disease and ulcerative colitis.

Our hsCRP test is in phase 2, late-stage technical development and includes working test cartridge prototypes that have demonstrated concordance with other laboratory predicate methods for quantified hsCRP determination across the clinically relevant range from a small blood sample collected on the blood collection sample wand. We have designed and developed the blood collector wand and its interface with the cartridge. We are currently completing development work prior to starting verification and validation studies, including scaling up manufacturing of the test chemistry pellet and blood collection wand, and increasing supply of other components needed for manufacture of the test. Clinical studies for the inflammation test are not driven by seasonality. We expect to start these studies in the second half of 2022 and, assuming successful completion of these studies, seek 510(k) clearance in 2023. Assuming we are successful in obtaining FDA clearance, we would expect to be able to commercialize this test shortly thereafter.

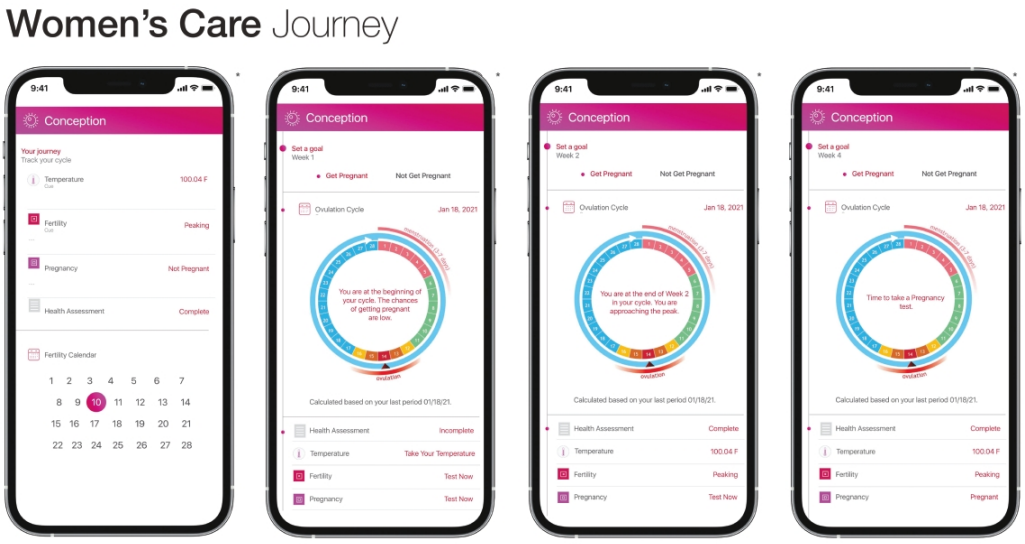
HbA1c

Early detection of heart disease risk through biomarker measurement can enable interception of the disease state and allow the individual the opportunity to make lifestyle changes. Glycated hemoglobin (HbA1c) is a important biomarker which is used to measure of the percentage of hemoglobin proteins in the blood which have glycated, or bound with sugar molecules. Elevated hemoglobin A1c (HbA1c) levels are strongly associated with an increased risk of cardiovascular disease (CVD) in people with and without diabetes. An HbA1C measurement reflects the average blood sugar levels over the previous 60-90 days which is used in conjunction with other factors to assess risk of cardiovascular disease.

Technical development for the Cue HbA1c test is in the chemistry proof of concept stage of the development phase. We have substantially completed the development of the test chemistry including screening and selection of antibody pairs and performed testing with relevant run, wash and detection buffers, using clinical blood samples. The HbA1c test shares the same the blood collector wand and cartridge interface as hsCRP.

Remaining development work includes optimizing the performance of the chemistry and biosensor components, scaling up manufacturing of the test chemistry pellet and blood collection wand, and increasing supply of other components needed for manufacture of the test.

Women's Health



* Depicts future product developments.

We believe that the women's health market around fertility, conception, and pregnancy monitoring could be well served with an integrated care solution that brings together the Cue Ecosystem Integrations and Apps layer for incorporating cycle monitoring, the Virtual Care Delivery App for connecting consumers to reproductive health specialist providers via telemedicine, and the Cue Health Monitoring System for occasional monitoring of the biomarkers indicative of ovulation, such as quantitative measurements of luteinizing hormone, and pregnancy detection via human chorionic gonadotropin (hCG).

Consumers who have reproductive health goals will have a natural alignment with enterprises that want to support their female employee workforce's personal goals, which promote employee satisfaction and do so in a way that minimizes the hassle of having to take time out of the workday for a significant number of in-person visits with reproductive health specialists. We believe that a woman's reproductive health journey can be made significantly more convenient and potentially more effective.

Some of the near-term priorities on the actual test cartridge development side include fertility testing via quantitative LH measurement, hCG detection for pregnancy test and post-conception support around quantitative hCG measurement for preeclampsia monitoring. Folic acid quantification will be a new area of development but we expect to be able to develop the test around a fingerstick of blood, rather than urine.

Fertility

Luteinizing hormone, or LH, plays a key role in the female reproductive system. LH levels increase or decrease at various stages of pregnancy, puberty, and ovulation. LH levels can indicate whether a woman is having problems with egg supply and consistent monitoring of LH levels can signal how fertile a woman is on different days of the menstrual cycle. While at-home LH tests are readily available, we believe our natively digital platform will provide a unique offering to accurately compare historical datapoints day-by-day and month-by-month. The sample type for our Cue LH test will be urine.

Our LH test is in phase 2, late-stage technical development. We have created and successfully tested LH test cartridges that are able to quantitatively determine LH levels in urine. We have completed the LH chemistry development and built multiple prototypes of the cartridge. Cartridges were tested using clinical urine samples and the relevant fluid Cue Wand, in the Cue Reader connected to the Cue App. The fluid collection Cue Wand for collecting urine has been designed, developed and successfully interfaces with the cartridges. The software for helping create the integrated care solution around the Cue Health Monitoring System requires further development. We have also built the manufacturing unit to mass produce the fluid collection wand.

We are currently completing development work prior to starting verification and validation studies, including scaling up manufacturing of the test chemistry pellet and fluid collection wand, and increasing supply of other components needed for manufacture of the LH test. Clinical studies for the LH test are not driven by seasonality. We expect to start these studies in the first half of 2022. LH tests for over-the-counter at-home use are exempt from the requirement for a 510(k). We intend to commercialize the LH test for over-the-counter at home use upon successful completion of our clinical studies. For professional use, assuming successful completion of our clinical studies, we expect to receive FDA clearance by the end of 2022 and, if we are able to obtain FDA clearance, to be able to commercialize this test shortly thereafter.

Pregnancy

Human chorionic gonadotropin, or hCG, is a hormone produced by the placenta of pregnant women. Early in pregnancy, the level of hCG increases in the blood and is eliminated in the urine. Detection of hCG in blood or urine confirms and rules out pregnancy, respectively.

Our hCG test is in phase 2, late-stage technical development. We have created and successfully tested hCG test cartridges that are able to qualitatively determine hCG levels above and below a pregnancy cutoff threshold. The sample type for our hCG test will be urine. We intend to continue to develop the test cartridge but consider this in an advanced stage of development. However, given the wide dynamic range required for quantitative hCG monitoring for preeclampsia, there is more work required to make the hCG test cartridges capable of effectively monitoring for preeclampsia. In addition, the software for helping create the integrated care solution around the Cue Health Monitoring System requires further development. We have completed the hCG chemistry development and built multiple prototype lots of cartridges. Cartridges were tested using clinical urine samples and the relevant fluid sample wand, in the Cue Reader connected to the Cue App. We are completing development work prior to starting verification and validation studies, including scaling up manufacturing of the test chemistry pellet and fluid collection wand, and increasing supply of other components needed for manufacture of the test. Clinical studies for our hCG test are not driven by seasonality. We expect to start these clinical studies in the first half of 2022. If the clinical studies are successful, we expect to submit for over-the-counter 510(k) clearance in the second half of 2022. Assuming we receive FDA clearance, we would expect to be able to commercialize this test shortly thereafter.

Men's Health

Testosterone

Although testosterone is the primary male sex hormone, both men and women require it for proper physical development. Testosterone is responsible for building muscle mass and strength, bone mass, and the production of red blood cells. Millions of people globally suffer from chronically low testosterone levels due to genetic, lifestyle, and environmental factors. If diagnosed, a healthcare provider can determine a treatment pathway to better regulate the patient's testosterone levels and improve their quality of life.

Testosterone levels follow diurnal patterns and vary throughout the day. They are typically at their peak in the morning and reach their lowest levels in the middle of the night. This diurnal pattern makes testing challenging, because measurements must be taken in the middle of the night. More convenient access to testosterone testing can allow monitoring of endogenous levels and determine if they remain within the age-specific normal range. This data can be utilized by the healthcare provider to better assess and treat the patient.

Technical development for the Cue free testosterone test is in the chemistry proof of concept stage of the development process. We have substantially completed the development of the test chemistry including screening and selection of antibody pairs and performed testing with relevant run, wash and detection buffers, using processed clinical saliva samples. The free testosterone test shares the same the fluid collection wand and cartridge interface as fertility and pregnancy. The Cue free testosterone test may be paired with a saliva processing device, which works to condition the saliva sample before it's loaded into the cartridge, without the use of laboratory equipment. Prototype saliva processing devices have been developed and tested in conjunction with the fluid wand.

Remaining development work includes optimizing the performance of the chemistry and biosensor components, scaling up manufacturing of the test chemistry pellet and fluid collection wand, and increasing supply of other components needed for manufacture of the test.

Wellness

Vitamin D

Vitamin D (25(OH) Vitamin D) is a hormone produced by the body when ultraviolet rays from sunlight strike the skin and trigger Vitamin D synthesis. Vitamin D helps regulate the immune system and the neuromuscular system and also plays major roles in the life cycle of human cells and to reduce the risk of osteoporosis. The prevalence of Vitamin D deficiency is high and often present in persons without any obvious risk factors.

To boost Vitamin D levels, many people take supplementation, either unmonitored or in concert with advisement from an HCP. Inappropriately high levels of vitamin D supplementation can lead to arterial calcification. A 25(OH) Vitamin D test result measures the levels of Vitamin D circulating in the body. Technical development for the Cue Vitamin D test is in the chemistry proof of concept stage of the development process. We have substantially completed the development of the test chemistry including screening and selection of antibody pairs, and performed testing with relevant run, wash and detection buffers, using clinical blood samples. The Vitamin D test shares the same the blood collector-style wand and cartridge interface as hsCRP.

Remaining development work includes optimizing the performance of the chemistry and biosensor components, scaling up manufacturing of the test chemistry pellet and blood collection wand, and increasing supply of other components needed for manufacture of the test.

Cortisol

Cortisol is a steroid hormone released from the adrenal glands in response to physical and psychological stressors. Cortisol helps to regulate stress response, nervous system function, and metabolism of fats, carbohydrates, and protein.

Measuring cortisol levels can help evaluate the function of pituitary and adrenal glands and can help diagnose conditions such as Cushing’s disease. Chronically elevated or deficient cortisol levels is associated with undesirable changes in body composition, immune response, and high blood pressure.

Technical development for the Cue cortisol test is in the chemistry proof of concept stage of the development process. We have substantially completed the development of the test chemistry including screening and selection of antibody pairs and performed testing with relevant run, wash and detection buffers, using processed clinical saliva samples. The cortisol test shares the same the fluid collection wand and cartridge interface as fertility and pregnancy. The Cue cortisol test may be paired with a saliva processing device, which works to condition the saliva sample before it’s loaded into the cartridge, without the use of laboratory equipment. Prototype saliva processing devices have been developed and tested in conjunction with the fluid wand.

Remaining development work includes optimizing the performance of the chemistry and biosensor components, scaling up manufacturing of the test chemistry pellet and fluid collection wand, and increasing supply of other components needed for manufacture of the test.

Vertically-Integrated Manufacturing Solutions

Our manufacturing facilities were developed alongside our science and technology and are vertically-integrated, fully automated and scalable. Our integrated manufacturing and bioproduction gives us complete control over the quality of our finished product.

We own and control the intellectual property that makes the platform possible. Our manufacturing process is replicable, and our manufacturing production pods can produce any type of test in our expected future test menu. We believe our manufacturing capabilities are differentiated and allow us not only to scale quickly and efficiently, but also to adapt our production quickly to market demands or evolving consumer needs.

We produce our Cue Cartridges in-house, including critical enzymes, antibodies, and primers for the test cartridges. We have complete production oversight and quality control over finished products and protection against global fluctuations in supply chain and costs. We achieve this by manufacturing all of our Cue Cartridges in our state-of-the-art facilities in San Diego, California using our modular, scalable production pods. Our fully automated production pods build raw components into fully assembled, packaged cartridges.

Our Cue Readers are manufactured by our partners. Our Cue Wands are manufactured by us or our partners. For our Cue Readers and Cue Wands, we own and control all of the intellectual property developed by us and rely on multiple suppliers.

On October 13, 2020, we announced a $480.9 million agreement with the U.S. DoD, on behalf of U.S. HHS, to expand our U.S.-based production capacity and deploy six million Cue COVID-19 Test Kits by March 2021, which agreement with the U.S. DoD was subsequently amended in March 2021 to require delivery by October 2021 and further amended in September 2021 to extend the date to December 31, 2021. This agreement included an upfront payment of $184.6 million to scale our manufacturing. This payment was intended to help us onshore our supply chain and rapidly increase our production capacity to enable and support domestic production of critical medical resources. In connection with this effort, we were able to rapidly scale our production, going from producing hundreds of Cue Cartridges per day to tens of thousands in a matter of months.

Reimbursement

We believe payment for our products, including our Cue COVID-19 Test Kits, will be billable by a physician, reimbursable by government payors or insurance companies, paid for by a self-insured employer, or eligible under FSA and HSA guidelines. For example, most of our contemplated future tests that are currently offered by others through central labs are reimbursable by third-party payors, including commercial health plans and governmental payors if properly ordered by a physician. These third-party payors decide which products will be covered and establish reimbursement levels for those products. Coverage criteria and reimbursement rates for clinical laboratory tests are subject to adjustment by payors, and current reimbursement rates could be reduced, or coverage criteria restricted in the future. We believe that the benefits of our portable, intuitive, accurate and connected system align incentives for all stakeholders, the user and the payors (self-insured employers and health plans), and that this will encourage payors to pay for or subsidize the Cue Health Monitoring System and associated tests for the end-user.

Coverage and reimbursement for our Cue COVID-19 Test Kit will vary by setting of care, payor type, and region. In the United States, we believe that healthcare providers that purchase our Cue COVID-19 Test Kit will likely look to various third-party payors, such as Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, accountable care organizations and other healthcare-related organizations, to cover and pay for our Cue COVID-19 Test Kit.

The Coronavirus Aid, Relief and Economic Security Act of 2020, or the CARES Act, provides coverage for EUA COVID-19 tests when such tests are medically appropriate and ordered by a healthcare provider. Presently, COVID-19 testing coverage exists for tests run in clinical laboratories and point-of-care settings. Under the first EUA we received, our COVID-19 test is eligible for reimbursement in point-of-care settings as a molecular point-of-care test.

CMS covers medically appropriate COVID-19 testing and currently reimburses $100 for high throughput laboratory tests to detect the SARS-CoV-2 virus if they return results within two days, $75 for such high throughput laboratory tests that take longer than two days to return results, $51 for such tests when not performed in high throughput laboratories (which would include our Cue COVID-19 Test Kit) and around $42 for antibody tests. However, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability. We have active engagement with the relevant federal agencies regarding reimbursement status of our Cue COVID-19 Test Kit. We continue to explore and enhance our coverage efforts with public and private payors.

Since we received an EUA for over-the-counter use in March 2021, we expect to receive payment directly from point-of-care customers and not to bill third-party payors directly. For point-of-care use, the success of our Cue COVID-19 Test Kit will depend substantially on the extent to which the costs of our Cue COVID-19 Test Kit will be covered by third-party payors, such as government health programs, commercial insurance and management healthcare organizations. These third-party payors decide which products will be covered and establish reimbursement levels for those products.

We believe that automation at scale would allow us to achieve a cost structure that would optimize value to the over-the-counter consumer and also reduce the impact of reimbursement on our sales.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for our commercially important technology, inventions and know-how, including our Cue Reader, our Cue Cartridge, and our Cue Wand; to defend and enforce our patents; to operate without infringing, misappropriating or violating the proprietary rights of others; and to prevent others from infringing, misappropriating or violating our

proprietary rights. We rely on a combination of patent, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have filed or may license or file in the future, and we cannot be sure that any patents we own or license or patents that may be licensed or granted to us in the future will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our test kits and technology. For more information regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

As of August 31, 2021, we owned twenty-one (21) issued U.S. utility patents, four (4) pending U.S. utility patent applications, thirty-five (35) issued foreign utility patents (including patents in Australia, Canada, China, Hong Kong, India, Israel, Japan, South Korea, South Africa, the United Kingdom, and various European countries), and twenty-eight (28) pending foreign utility patent applications (including pending PCT applications).

Our utility patents and patent applications are directed to many different aspects of our platform. By way of example, our granted patents and pending patent applications cover various structural features of our Cue Cartridge, sensors within the Cue Cartridge for use in detecting target analytes, systems and methods for analyte detection and quantification, and our Cue Reader.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term for a utility patent is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. Our issued U.S. and foreign utility patents are anticipated to naturally expire between 2034 and 2036, and our U.S. pending utility patent applications and pending PCT applications, if issued into patents, are anticipated to naturally expire between 2034 and 2041, excluding any additional patent term adjustment(s) or extension(s), and assuming payment of all applicable maintenance or annuity fees. Once a patent expires, patent protection ends and an invention enters the public domain allowing anyone to commercially exploit the invention without infringing the patent.

In addition, we hold design patents and patent applications that cover various ornamental features of our Cue Reader, our Cue Cartridge, and our Cue Wand. As of August 31, 2021, we owned nine (9) granted U.S. design patents, two (2) pending U.S. design patent applications, thirty-six (36) granted foreign design patents and design registrations (with protection in Canada, China, Japan, the United Kingdom, and the European Union), and four (4) pending foreign design applications. Our granted U.S. design patents are anticipated to naturally expire between 2029 and 2036. Our foreign design patents and design registrations are anticipated to naturally expire between 2024 and 2042.

We cannot guarantee that patents will be issued from any of our pending applications or that issued patents will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop methods or devices that are not covered by our patents or circumvent these patents. Furthermore, because patent applications can take many years to publish, there may be applications unknown to us which may result in issued patents that our existing or future products or technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. We may need to engage in litigation to enforce patents issued to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Such litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer’s competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from manufacturing, selling or using the product determined to be infringing, any of which could harm our business. See “Risk Factors—Risks Related to Our Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio.

We also rely upon trademarks to build and maintain the integrity of our brand. As of August 31, 2021, we owned three (3) U.S. trademark registrations, forty-four (44) foreign trademark registrations (including registrations in China, Hong Kong, the European Union, India, Israel, Japan, Mexico, Russia, South Korea, and Singapore), and two (2) pending trademark applications in Mexico. We also rely, in part, on unpatented trade secrets, know-how,

continuing technological innovation, and confidential information, to develop and maintain our competitive position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. However, such proprietary rights are difficult to protect. We seek to protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants and others who may have access to our proprietary information. However, these agreements may not provide meaningful protection. These agreements may be breached, and we may not have an adequate remedy for any such breach. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have implemented measures to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our Cue Health Monitoring System or any of our current or expected future tests or to obtain or use information that we regard as proprietary. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Competition

We do not believe there are currently any competitors that offer the portable, intuitive, accurate and connected platform provided we provide, comprised of the Cue Health Monitoring System and associated tests, our Cue Health App and our Cue Enterprise Dashboard. That said, the traditional diagnostic testing industry is highly competitive and rapidly changing. For our Cue COVID-19 Test specifically, we expect ongoing intense competition from different sources, including from manufacturers and producers of diagnostic tests, as well as vaccines and therapeutic treatments that may decrease demand for COVID-19 tests. Notably, however, we are the first molecular COVID-19 test approved for at-home and over-the-counter use without a prescription. As we broaden our test menu, we expect ongoing intense competition from companies that develop or have already developed molecular tests, whether for at-home and over-the-counter use or at the point-of-care, as well as companies that have or are developing antigen and antibody tests. While we believe that our differentiated technology, customer-centric design, and vertically-integrated manufacturing provide us with competitive advantages, we face potential competition from many different sources, including public and private companies, academic institutions, public and private research institutions and governmental agencies.

Competitors with diagnostic testing platforms include private and public companies, such as Abbott Laboratories, Becton, Dickinson and Company, BioMerieux SA, Bio-Rad Laboratories, Inc., Danaher Corp., Ellume Limited, Everly Health, Inc., F. Hoffman-La Roche Ltd., Fluidigm Corporation, GenMark Diagnostics Inc., Ginkgo Bioworks, Inc., Mammoth Biosciences, Inc., LetsGetChecked, Lucira Health, Inc., Qiagen N.V., Quidel Corporation, Sherlock Biosciences, Inc., Siemens AG, Talis Biomedical Corporation, Thermo Fisher Scientific, Inc. and Visby Medical, Inc. as well as several retailers, such as The Kroger Company, Walmart Inc. and Alberstons Companies, Inc. Large lab companies like Quest Diagnostics, Inc. and Laboratory Corporation of America have also expanded beyond centralized laboratory testing into at-home sample collection.

As we expand our service offerings, we anticipate integrating with a variety of technology platforms. These platforms may have products or services that compete with our offerings, and include companies such as 1Life Healthcare, Inc. (d/b/a OneMedical), American Well, Inc., Hims & Hers Health, Inc., and Teladoc Health, Inc. We may also face competition from other companies, including other technology companies. For example, it has been public reported that Amazon.com, Inc. may be considering launching an at-home diagnostic testing business.

Many of the companies we currently compete with or which we may compete with in the future have significantly greater financial resources and more experience in research and development, manufacturing, pre-clinical and clinical development, obtaining regulatory approvals and marketing approved tests. Smaller or early-stage companies may also prove to be significant competitors, whether independently or with strategic partners. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and enrolling subjects for our clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We believe key competitive factors impacting our success in the market include accuracy of results, ease-of-use, accessibility, time to result, clinical performance, pricing, ability to meet consumer demand, and reimbursement levels.

Employees and Human Capital Resources

As of August 31, 2021, we had 1,254 full-time employees. Our employees are primarily located in the San Diego, California area. None of our employees are represented by a labor union or are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

We follow Good Manufacturing Practice, or GMP, guidelines and are ISO 13485 certified, the key certification for medical device manufacturing, providing confidence and assurance in our final product. We are routinely audited to maintain our ISO 13485:2016 status.

During the fall of 2020, we launched a significant expansion of our manufacturing capacity, leasing an approximately 197,000 square-foot facility in Vista, California and an approximately 63,000 square-foot facility in San Diego, California. As of August 31, 2021, the Vista facility was producing cartridges from six production pods (with space for an additional four production pods) and is serving as our warehousing and distribution hub. Our Waples facility will serve as a second reagent production hub, house certain cartridge component manufacturing, and has space for five production pods, all of which are currently in operation. Our Nancy Ridge facility is also producing cartridges from two production pods. We believe our current facilities are sufficient to meet our current needs, and that we will be able to find appropriate space for expansion when appropriate. Our Vista facility lease expires on July 1, 2026 and our Waples facility lease expires on July 1, 2031. Both leases have options to extend.

Government Regulation

Regulation of Medical Devices in the United States

Our product and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and its implementing regulations, collectively referred to as the FDCA, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export and post-marketing surveillance.

The FDA regulates the development, design, pre-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending premarket applications, issuance of warning letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval, or PMA, or grant of a de novo request for classification. During public emergencies, the FDA also may grant emergency use authorizations, or EUA, to allow commercial distribution of devices intended to address the public health emergency. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to provide reasonable assurance of its safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device.

Class I devices include those with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's "general controls" for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions through the submission of Medical Device Reports, or MDRs, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I or low risk devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are moderate risk devices subject to the FDA's general controls, and any other "special controls" deemed necessary by the FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. When required, the manufacturer must submit to the FDA a premarket notification, or 510(k), submission demonstrating that the device is "substantially equivalent" to a legally marketed predicate device, which in some cases may require submission of clinical data. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous premarketing requirements.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices and devices deemed not substantially equivalent to a predicate device following a 510(k) submission. The safety and effectiveness of Class III devices cannot be reasonably assured solely by general or special controls. Submission and FDA approval of a PMA application is required before marketing of a Class III device can proceed. As with 510(k) submissions, unless an exemption applies, PMA submissions are subject to user fees. The PMA process is much more demanding than the 510(k) premarket notification process. A PMA application, which is intended to demonstrate that the device is reasonably safe and effective for its intended use and must be supported by extensive data, typically including data from pre-clinical studies and clinical trials.

The FDA also has the authority to allow the commercialization of unapproved medical devices, or new uses of existing devices in times of emergency, such as during a pandemic.

Emergency Use Authorization

In emergency situations, such as a pandemic, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear warfare threat agents when there are no adequate, approved, and available alternatives.

Under this authority, the FDA may issue an EUA for an unapproved device if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence of effectiveness of the device exists; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no other alternatives exist for diagnosing, preventing or treating the disease or condition. Evidence of effectiveness includes medical devices that "may be effective" to prevent, diagnose, or treat the disease or condition identified in a declaration of emergency issued by the Secretary of U.S. HHS. The "may be effective" standard for EUAs requires a lower level of evidence than the "effectiveness" standard that FDA uses for product clearances or approvals in non-emergency situations. The FDA assesses the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, in vivo efficacy data from animal models, in vitro data, as well as the quality and quantity of the available evidence.

Once granted, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of U.S. HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

On January 31, 2020, the Secretary of U.S. HHS issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, U.S. HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020, that circumstances exist to justify the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. On February 29, 2020, the FDA issued an immediately in effect guidance with policy specific to development of in vitro diagnostic tests during the COVID-19 public health emergency. This guidance was updated on March 16, 2020, May 4, 2020 and May 11, 2020.

We received an EUA from the FDA on June 10, 2020 for our Cue COVID-19 Test Kit for use at the point-of-care with specimens collected using the Cue Wand from individuals who are suspected of having COVID-19 by their healthcare provider. On August 20, 2020, the FDA granted an amendment to our EUA to add testing of previously collected nasal specimens in viral transport media from individuals who are suspected of having COVID-19 by their healthcare provider.

In September 2020, the FDA required us to evaluate the analytical limit of detection and to assess the traceability of our Cue COVID-19 Test with FDA reference materials, which requirements we have complied with. Additionally, in September 2020, we submitted a post-market clinical data report required under our EUA, which included results from the Mayo Clinic's evaluation of Cue versus an institutional reference panel. The FDA subsequently notified us that our post-market study and report were sufficient to satisfy the conditions in our EUA.

We received a second EUA from the FDA on March 5, 2021 for our Cue COVID-19 Test Kit for home and over-the-counter use without a prescription with specimens collected using the Cue Wand from adults or children greater than or equal to two years of age (swabbed by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19.

510(k) Clearance Marketing Pathway

Our current products are Class II and, but for the immediate ability to seek an EUA, would be subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a 510(k) submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A legally marketed predicate device may include a device that was legally marketed prior to May 28, 1976 (a pre-amendment device), a device that has been reclassified from Class III to Class II or Class I, or a device that was found substantially equivalent through the 510(k) process. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (1) the same technological characteristics, or (2) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. A showing of substantial equivalence sometimes, but not always, requires clinical data. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 calendar days to review and issue a determination. As a practical matter, clearance may take and often takes longer. Upon review, the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. For fiscal year 2021, the standard user fee for a 510(k) premarket notification application is $12,432.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information within 180 days before the FDA will proceed with additional review of the submission.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, for example, due to a finding of a lack of a predicate device, that the

device has a new intended use or different technological characteristics that raise different questions of safety or effectiveness when the device is compared to the cited predicate device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. If the FDA determines that the information provided in a 510(k) submission is insufficient to demonstrate substantial equivalence to the predicate device, the FDA generally identifies the specific information that needs to be provided so that the FDA may complete its evaluation of substantial equivalence, and such information may be provided within the time allotted by the FDA or in a new 510(k) submission should the original 510(k) submission have been withdrawn.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) submission is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) marketing clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. More recently, in September 2019, the FDA finalized the aforementioned guidance to describe an optional "safety and performance based" pre-market review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list of device types appropriate for the "safety and performance based pathway" and develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

We expect that many of our future tests will require clearance under the 510(k) regulatory pathway, unless otherwise authorized pursuant to and EUA.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is generally more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is reasonably safe and effective, and the PMA must be supported by extensive data, including data from pre-clinical studies and clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review may take and often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may

not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical trial that supported PMA approval or requirements to conduct additional clinical trials post-approval. The FDA may also condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, that affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

None of our tests are currently approved under a PMA, nor are we currently seeking approval under a PMA for our Cue COVID-19 Test or any additional test. However, we may in the future develop devices which will require the approval of a PMA.

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. To market low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, a manufacturer may request a de novo down-classification. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. A medical device may be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 calendar days following receipt of the de novo application, although in practice, the FDA's review may take significantly longer. During the pendency of the FDA's review, the FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the de novo request for classification if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. In the event the FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request for classification. When the FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

Clinical Trials

Clinical trials are typically required to support a PMA, oftentimes for a de novo request for classification, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must be approved prior to commencing clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, purported or represented to be used in supporting or sustaining human life, is for a use that is substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A clinical trial may begin 30 days after receipt of the IDE by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Acceptance of an IDE application for review does not guarantee that the FDA will approve the IDE and, if it is approved, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

In addition, the clinical trials must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA.

If the device is considered a "non-significant risk," IDE submission to FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required. Abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements also apply to non-significant risk device studies.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical trial are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all applicable reporting and record keeping requirements.

Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, there can be no assurance that the data generated during a clinical trial will meet the safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers and contract manufacturers, including any third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or "off-label" uses of cleared or approved products;

- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections, product removals or recalls if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In general, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Manufacturing processes for commercial products are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, design history file, device history records, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products, which would harm our business. The discovery of previously unknown problems with any of our Cue Health Monitoring Systems or any of our tests, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, withdrawal, administrative detention or seizure of our Cue Health Monitoring System or any of our current or future test cartridges;
- operating restrictions or partial suspension or total shutdown of production;
- refusal of or delay in granting our requests for 510(k) clearance or PMA approval of new tests or modified tests;
- operating restrictions, partial suspension or total shutdown of production;

- withdrawing 510(k) clearance or PMA approvals that are already granted;
- refusal to grant export approval for our Cue Health Monitoring System or any of our current or future tests; or
- criminal prosecution.

Clinical Laboratory Improvements Amendments of 1988

CLIA Regulations Relating to In Vitro Diagnostic Tests

The Cue Health Monitoring system and our Cue COVID-19 Test also are subject to categorizaion by the FDA pursuant to CLIA and its implementing regulations in the United States which establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. A laboratory is broadly defined to include any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA regulations establish standards for proficiency testing; facility administration; general laboratory systems; pre-analytic, analytic systems, post-analytic systems; personnel qualifications and responsibilities; quality control, quality assessment; and specific provisions for laboratories performing moderate to high complexity tests.

The regulations promulgated under CLIA establish three levels of in vitro diagnostic tests: (1) waived; (2) moderately complex; and (3) highly complex. When a test is categorized as waived, it may be performed by laboratories that have a Certificate of Waiver.

Tests that are waived by the CLIA regulations are automatically categorized as waived following 510(k) clearance or PMA approval. Otherwise, following clearance or approval, the FDA will classify in vitro diagnostics in accordance with the CLIA regulations. Manufacturers of clinical laboratory test systems, such as in vitro diagnostics, that are categorized as moderate complexity according to the CLIA categorization criteria may request categorization of the text as waived through a CLIA Waiver by Application submission to FDA. Waived tests are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or (B) FDA has determined pose no reasonable risk of harm to patients if the examinations or procedures are performed incorrectly. These tests are waived from regulatory oversight of the user other than the requirement to follow the manufacturer’s labeling and directions for use. Further, when FDA authorizes tests for use at the point-of-care under an EUA, such tests are deemed to be CLIA waived tests. As such, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver for the duration of the emergency declaration. We are also required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. We provide testing services only to our employees, visitors, and contractors and do not provide laboratory testing services for purposes other than operation of our business.

Licensing and Regulation of Medical Device Manufacturers and Distributors

We are licensed by the California Department of Public Health as a medical device manufacturer. As a medical device manufacturer, one of the criteria is that Our Quality Management System, or QMS, holds an ISO 13485:2016 certificate. The ISO is an independent, non-governmental international organization that defines world-class specifications for products, services and systems, to ensure quality, safety and efficiency. ISO 13485:2016 is a harmonized, international regulatory benchmark for quality management systems that addresses most or all of the QMS requirements in markets including the United States, European Union, Australia, Japan and Canada. The ISO 13485:2016 certificate confirms that an organization operates a QMS that conforms to the standards established by ISO. The FDA recently proposed a rule to harmonize and modernize its QSR, which would supplant the existing requirements with ISO 13485:2016.

In addition, we may be required to obtain additional licenses as we increase our direct sale and distribution of tests. Medical device manufacturers who distribute over-the-counter devices are subject to complex and varying state licensing requirements that can attach to their manufacturing and/or distribution activity. While some states have no licensing regimen for medical device manufacturing and distribution at all, others, such as California, regulate certain types of distribution activity. For example, California separately licenses home use medical device retail facilities.

Massachusetts has codified a Code of Conduct that applies to any entity that employs or contracts with any person to sell or market prescription drugs or medical devices in Massachusetts. In preparation for our expansion of direct marketing of its home use tests, we are reviewing state regulatory requirements that may apply to us as a medical device manufacturer or distributor.

European Medical Device Regulation

Sales of in vitro diagnostics in the European Economic Area are subject to the European regulatory framework. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. Set forth below are highlights of the key European regulatory schemes applicable to our business.

European Conformity Marking ("CE Mark") and Certifications

In order to place an in vitro diagnostic, or an accessory to an in vitro diagnostic, on the market in the European Union/European Economic Area, the device must be designed, developed, manufactured, and marketed in compliance with the relevant legal framework. Currently, in vitro diagnostics must be compliant with Directive 98/79/EEC, or the Directive; however, from May 26, 2022 Regulation (EU) 2017/746, or the Regulation, will replace the Directive. While the Regulation will have direct effect in all European Economic Area countries, the Directive required national implementing legislation in each country, which had historically led to some variation in the regimes in each country.

Prior to May 26, 2022, in vitro diagnostics that have been assessed for conformity with the requirements of the Directive, including notably the "essential requirements" set out in Annex I of the Directive, are entitled to bear a CE Mark indicating that the device conforms to the standards required by the Directive. In vitro diagnostics that have been CE marked may be placed on the market throughout the Member States of the European Union and the European Economic Area, and other countries that comply with or mirror the Directive.

The method of assessing conformity of in vitro diagnostics will depend on the type and classification of the in vitro diagnostic. For in vitro diagnostics that are in the lowest risk classification (meaning that they do not appear in the list set out in Annex II of the Directive nor are they used for the purpose of self-testing by the user/patient), the manufacturer can self-assess that the in vitro diagnostics comply with the essential requirements in the Directive without any review or intervention by any regulatory body and/or third-party. In doing so, the manufacturer must comply with Common Technical Specifications adopted by the European Commission for certain diagnostic tests, unless they can justify not doing so. The manufacturer may choose to comply with harmonized technical standards adopted by European standards bodies. Although compliance with these standards is not mandatory, compliance raises a presumption of conformity with the essential requirements that each standard addresses.

Once the manufacturer has gathered the technical documentation necessary to demonstrate this in the form of a technical file, it must draw up a declaration of conformity and can then affix a CE Mark to the device and place it on the market. The only additional requirements are (i) that the manufacturer (or its authorized representative if the manufacturer is outside the European Economic Area) must maintain a copy of the relevant technical file, so that it can be inspected by national device regulators; (ii) that the manufacturer and, where relevant, its authorized representative must register themselves and their in vitro diagnostics, so that these authorities know when the products are to be marketed; and (iii) that the manufacturer must perform device vigilance to monitor the safety and performance of the in vitro diagnostics on the market, reporting both adverse incidents and any field safety corrective actions, or FSCAs, to the authorities, as appropriate. Challenges by European regulatory authorities may arise subsequently if there is an issue related to the compliance, safety or performance of the device. Such challenges may arise from a routine audit or enquiry by a regulatory authority or following device vigilance reports by the company or others, or reports of FSCAs by the company, or complaints made by competitors.

Under the Directive, any in vitro diagnostic that is for self-testing or that appears in Annex II (meaning that these devices cannot use the self-certification process) must have their compliance with the Directive reviewed and certified by a European Notified Body. Notified bodies are usually private, non-governmental, independent bodies that are authorized/licensed by governmental authorities to perform conformity assessments. They enter into a contractual arrangement with manufacturers to carry out the conformity assessment of in vitro diagnostics. The Notified Body will review the technical documentation, including assessing the available clinical evidence, literature data for the product and any available post-market experience. There is some flexibility regarding the conformity assessment procedure the manufacturer uses. If the manufacturer decides to base its conformity assessment on an

assessment of its Full Quality Assurance System (rather than a more product-focused "Type Examination"), the Notified Body will also perform an audit of the manufacturer's quality system against an international standard, EN ISO 13485:2016. If the Notified Body deems the in vitro diagnostic (and where applicable the manufacturer's quality system) conforms to the Directive it will issue a certificate of conformity for the device and, where applicable, a certificate of conformity for the manufacturer's quality system, which the manufacturer can use as the basis for its declaration of conformity, then affix a CE Mark and thus place the in vitro diagnostic on the market in the European Union / European Economic Area.

On May 26, 2017 the Regulation entered into force and, from May 26, 2022, the Regulation will apply and will replace the Directive. From that date, in vitro diagnostics should have been assessed for conformity with the Regulation and should not be CE marked and placed on the market unless they are in compliance. However, the Regulation provides for a transition period that allows manufacturers or products that benefit from certificates of conformity issued by European Notified Bodies under the Directive prior to May 26, 2022 to continue to place those products on the market until May 26, 2024. Where they have been placed on the market prior to that date, they may then be distributed and supplied to end-users until May 26, 2025. However, this transition period does not apply to in vitro diagnostics that have undergone manufacturer self-certification nor does it to products that benefit from Notified Body certificates of conformity but where the manufacturer has made significant changes to a device since the certificate was issued. These products must be in compliance with the Regulation from May 26, 2022, or from the date of the change if that occurs prior to May 26, 2024.

As with the Directive, the Regulation requires that in vitro diagnostics must undergo a conformity assessment procedure, have a declaration of conformity drawn up and bear the CE Mark before a manufacturer can place them on the European Union / European Economic Area market. However, the Regulation will up-classify many in vitro diagnostics that the Directive currently allows manufacturers to self-assess and declare conformity, so that the vast majority of in vitro diagnostics, including all diagnostic tests, will require a European Notified Body conformity assessment as part of the conformity assessment process. In practice, manufacturers may only be able to self-assess and declare the conformity of consumables and apparatus that are regulated as in vitro diagnostics but are not the tests themselves. The Regulation will also provide for greater use of common specifications that are presumed to be binding, unless a manufacturer can justify not doing so.

Following the United Kingdom's departure from the European Union on January 31, 2020, the United Kingdom continued to follow the same regulations as the European Union during a Transition Period until the end of 2020. Now that the Transition Period has ended, the United Kingdom has implemented Directive 98/79/EC into U.K. law (along with other European Union legislation on medical devices) through the Medical Devices Regulations 2002. Therefore, the two regulatory systems are independent but currently broadly aligned (although under the Northern Irish Protocol, the European Union regulatory framework will continue to apply in Northern Ireland). The United Kingdom has implemented certain new regulatory requirements, including that all medical devices and in vitro diagnostics must be registered with the Medicines and Healthcare products Regulatory Authority before being placed on the market in Great Britain. There is a grace period to allow time for compliance with the new registration process, with higher risk devices (i.e. List A products) requiring registration by May 1, 2021, and lower risk devices requiring registration later in 2021 (List B products from September 1, 2021 and general in vitro diagnostics from January 1, 2022). CE marking will continue to be recognized in Great Britain for medical devices until June 30, 2023, following which a UK Conformity Assessment mark will be required for a medical device or in vitro diagnostic device to be marketed in Great Britain. The new European Union medical device and in vitro diagnostics regulations will not apply in Great Britain and it remains uncertain at present how the U.K. regulatory regime will change in future and the extent to which it will diverge from European Union regulations.

Privacy Regulation

U.S. Privacy Regulation

The privacy and security regulations under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, collectively referred to herein as HIPAA, establish uniform standards governing the conduct of certain electronic healthcare transactions and require covered entities, such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective business associates, as well as their covered contractors, that perform services for them which involve the creation, receipt, use, maintenance, transmission or disclosure of, individually identifiable health information for or on behalf of a covered entity, to comply with standards that relate to the privacy and security of protected health information, or PHI. HIPAA also sets forth certain rights that an individual may have with respect to his or her PHI maintained by a covered entity,

including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. HIPAA's breach notification provisions require covered entities to report breaches of PHI that have not been encrypted or otherwise secured in accordance with guidance from the Secretary of the U.S. HHS. Required breach notices must be made as soon as is reasonably practicable, but no later than sixty (60) days following discovery of the breach. Reports must be made to affected individuals and to the Secretary of the U.S. HHS and, in some cases depending on the size of the breach, they must be reported through local and national media. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates, which are independent contractors or agents of covered entities that create, receive, maintain or transmit PHI in connection with providing a service on behalf of the covered entity. These agreements require business associates to safeguard the covered entity's PHI against improper use and disclosure. Certain of HIPAA's privacy and security standards are directly applicable to business associates. In the event we begin to bill health plans or health insurers for our Cue Health Monitoring System and our associated tests, using standard electronic transactions, we would become a covered health care provider subject to HIPAA. Because we maintain PHI on behalf of the laboratories that are covered entities and conduct testing with the Cue COVID-19 Test, and we create, receive, maintain, and use or disclose PHI on our behalf, we are considered a business associate subject to certain provisions of HIPAA and the terms of any business associate agreements we enter into with such healthcare providers or health plans and our vendors that may access, use or disclose PHI. Covered entities and business associates may be subject to significant civil and criminal penalties for noncompliance with HIPAA. Both the Office for Civil Rights within the U.S. HHS and state attorneys general have authority to enforce HIPAA.

In addition, various states in the United States have laws and regulations governing the use and disclosure of health information, such as the California Confidentiality of Medical Information Act; these laws are not preempted by HIPAA to the extent they are more stringent than HIPAA. These laws frequently change, and we may not be able to maintain compliance in all jurisdictions in which we do business. To the extent that any of these laws were to apply to medical device manufacturers or mobile applications, we would be required to comply. However, other than the Confidentiality of Medical Information Act, or CMIA, which governs mobile applications, most of these laws apply to either health care providers or certain sensitive information, such as sexually transmitted diseases. If we were to obtain approval for tests which involved the collection and maintenance of sensitive information, we may be subject to laws in certain jurisdictions. These laws frequently change, and we may not be able to maintain compliance in all jurisdictions in which we do business.

Specifically, the CMIA deems to be a "health care provider" subject to its requirements any business that, as one of its purposes, maintains medical information for health care providers or individuals, or offer mobile applications or other related devices to consumers that maintains medical information in order to make the information available to an individual or a provider of health for purposes of allowing the individual to manage his or her information, or for the diagnosis, treatment, or management of a medical condition, in addition to other types of entities. Further, under CMIA, an affected individual whose privacy is breached has a private right of action for actual or nominal damages.

Additionally, the FTC and many state attorneys general are interpreting existing federal and state consumer protection laws (including online privacy laws) to impose evolving standards for the online collection, use, dissemination and security of health-related and other personal information.

State laws, such as the California Online Privacy Protection Act, similarly regulate such practices for mobile applications. Consumer protection laws such as these require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices at the federal or state level, which could lead to significant liabilities and consequences. Furthermore, according to the FTC violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act.

We seek to utilize biological samples and data from participants in our clinical trials in accordance with applicable law, IRB stipulations, and participant permissions (through consent forms and HIPAA authorizations). If we are unable or significantly restricted in using participant samples and data for secondary research purposes, our ability to develop additional products and/or improve or refine existing products will be limited, which may impact our business and prospects.

The California Consumer Privacy Act, or the CCPA, became effective in January 2020 and imposes many requirements on covered businesses that collect or process the personal information of California residents, including providing notice to data subjects regarding the information collected about them and providing data subjects the right to restrict the use of their personal information and to request access to or removal of such personal information. The CCPA contains significant penalties for companies that violate its requirements. The CCPA currently excepts HIPAA covered entities, business associates, or health care providers subject to CMIA. In addition, many states have enacted laws that impose fines on entities that experience a data breach involving certain types of personal data, permit consumers to bring private actions against parties that experience a breach involving their data or requiring notification of data subjects and state authorities in the event of a data breach. Further, the California Privacy Rights Act, or the CPRA, was recently voted into law by California residents. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. We may become subject to laws such as CCPA and CPRA in the future, in relation to some of the personal information that our business holds on customers and/or our employees. If we violate any of these laws applicable to our operations, we could face significant financial penalties and reputational damage.

There are also foreign privacy and security laws and regulations that impose restrictions on the access, use, and disclosure of personal information. As a business that operates both internationally and throughout the United States, any wrongful use or disclosure of personally identifiable information, even if it does not constitute PHI, by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business or impose additional costs on our operations, including the cost of providing credit monitoring and identity theft prevention services to affected consumers.

If we or our operations are found to be in violation of HIPAA, as amended by HITECH or their implementing regulations, and similar state laws, we may be subject to significant penalties, including civil, criminal and administrative penalties, fines, imprisonment, and the curtailment or restructuring of our operations. HIPAA has four tiers of civil monetary penalties, as well as criminal penalties, both of which may be applied to business associates as well as covered entities, and state attorneys have authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. State privacy and security laws also may include penalties for noncompliance, as well as a private right of action.

General Data Protection Regulation and the United Kingdom Data Protection Act 2018

The General Data Protection Regulation (Regulation (EU) 2016/679), the GDPR, and the U.K. General Data Protection Regulation or the U.K. GDPR, and the U.K. Data Protection Act 2018 or the U.K. DPA, and other related privacy and data protection legislation in the jurisdictions in which we operate impose strict requirements on controllers and processors of personal data, including special protections for sensitive personal data categories, which include health and genetic information of data subjects residing in the European Union or the United Kingdom. The GDPR and the U.K. GDPR and U.K. DPA impose several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR and the U.K. GDPR and U.K. DPA grant individuals the opportunity to object to the processing of their personal data, allows them to request deletion of personal data in certain circumstances, and provides an individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR and the U.K. GDPR and U.K. DPA impose strict rules on the transfer of personal data out of the European Economic Area (or the United Kingdom) (i.e. to "third countries") to the United States or other regions that have not been deemed to offer "adequate" privacy protections under their domestic laws. The GDPR and the U.K. GDPR and U.K. DPA may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with European Union and U.K. data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and the U.K. GDPR and U.K. DPA and related privacy and data protection legislation may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR and the U.K. GDPR and U.K. DPA have introduced substantial fines for breaches of the data protection rules, increased powers

for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress (the maximum fine is the higher of €20 million (or £17.5 million in the United Kingdom) or 4% of the total annual worldwide turnover in the preceding financial year). We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR or the U.K. GDPR and U.K. DPA and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

The GDPR and the U.K. GDPR and U.K. DPA are complex laws and the regulatory guidance is still evolving, including with respect to how the GDPR and the U.K. GDPR and U.K. DPA should be applied in the context of transactions from which we may gain access to personal data. Data protection authority activity differs across the European Union between member states (and the United Kingdom), with certain authorities applying their own agenda which shows there is significant uncertainty in the manner in which data protection authorities will seek to enforce compliance with GDPR in the medical and research fields. For example, it is not yet clear if such authorities will conduct random audits of companies subject to the GDPR or the U.K. GDPR and U.K. DPA or will only respond to complaints filed by individuals who claim their rights have been violated. Enforcement actions to date in other industries has resulted in significant fines and other penalties. Failure to comply with the requirements of the GDPR and the related national data protection laws of European Union member states, which may deviate slightly from the GDPR, or the U.K. GDPR and U.K. DPA, may result in material fines.

Other International Privacy and Security Regulations

Our business is subject to a complex and evolving global web of laws and regulations governing data privacy, data security, cross-border data transfers, and data localization. Federal, state, local, and foreign governments are increasingly implementing or expanding their data protection regimes, resulting in additional compliance costs and risks. Many of these laws and regulations are subject to change and uncertain interpretation, and could result in regulatory or litigation claims or actions, changes to our business practices, monetary penalties, increased cost of operations, declines in clinical study participation or engagement, or otherwise harm our business.

We rely on information technology systems, including third-party hosted services, to support our business processes and activities and to store personal data (including employee and patient data). Consequently, we are at risk of a cybersecurity-related attack, intrusion, or disruption, including by criminal organizations, hackers, foreign governments, and terrorists. A cybersecurity incident could result in some or all of our systems being unavailable; the loss, misuse, or unauthorized disclosure of personally identifiable information or other personal data; negative publicity and reputational damage; exposure to risk of loss; and litigation and regulatory investigations. In the event we are a victim of a cyberattack, data breach notification laws may require us to notify regulators, affected individuals, and potentially other third parties in multiple jurisdictions. Cyber threats are constantly evolving, increasing the difficulty of detecting and successfully defending against them. Despite our security measures, we cannot guarantee that these measures will prevent all possible security breaches or attacks.

U.S. Federal, State and Foreign Fraud and Abuse Laws

U.S. Federal and State Fraud and Abuse Laws

The U.S. federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order, arrangement for, or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The definition of “remuneration” has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. The government takes the position, and courts have agreed with the government’s interpretation, that the statute’s intent requirement is satisfied if any one purpose of an arrangement involving

remuneration is to induce referrals of federal healthcare covered businesses, even if there are other legitimate purposes. Violations of the federal Anti-Kickback Statute can result in criminal penalties and fines, imprisonment of up to ten years, civil and administrative penalties for each violation, damages, and exclusion from participation in federal healthcare programs like Medicare or Medicaid. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or the FCA, discussed in greater detail below.

There are a number of statutory exceptions and regulatory "safe harbors" protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance to offer protection. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the U.S. HHS, Office of the Inspector General, or the OIG.

Many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Laws. The federal false claims and civil monetary penalties laws, including the Civil Monetary Penalties Law, and the FCA prohibit any person or entity, among other things, to knowingly present, or cause to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. The qui tam provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program.

When an entity is found to have violated the FCA, it may be required to pay treble damages and significant mandatory penalties, civil monetary penalties, and may be subject to exclusion from participation in federal healthcare programs such as Medicare and Medicaid. Many medical device manufacturers and healthcare companies have reached substantial financial settlements with the federal government for a variety of alleged improper activities and have entered into corporate integrity agreements with OIG, under which the companies undertake certain compliance, certification and reporting obligations, to avoid exclusion from federal health care program. The federal government has used the FCA to assert liability on the basis of kickbacks, or in instances in which manufacturers have provided billing or coding advice to providers that the government considered to be inaccurate. In these cases, the manufacturer is subject to liability for "causing" a false claim. In addition, the federal government has pursued companies under the FCA in connection with off-label promotion of products. Our activities, including those relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our Cue Health Monitoring System and any of our future tests (once approved) and the sale and marketing of our tests (once approved), may be subject to scrutiny under the federal Anti-Kickback Statute and the FCA. We are also subject to other criminal federal laws that prohibit making false or fictitious claims and false statements to the federal government.

While we are unaware of any current investigations or allegations for violations of anti-kickback or false claims laws, we are unable to predict whether we will be subject to actions under the FCA or a similar state law, or the impact of such actions. However, the costs of defending such claims, even if successful or if any sanctions imposed, could significantly affect our business as well as our financial performance.

HIPAA Fraud Statute. HIPAA, among other things, imposes criminal liability for knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement

or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The federal physician self-referral law, commonly known as the Stark Law, prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain "designated health services" (including clinical laboratory services) if the referring physician or a member of the physician's immediate family has a direct or indirect financial relationship (including an ownership interest or a compensation arrangement) with the entity, unless an exception applies. The Stark Law is a strict liability statute, which means intent to violate the law is not required. Penalties for violating the Stark Law may include: denial of payment for services ordered in violation of the law, recoupments of monies paid for such services, civil monetary penalties, and exclusion from participation in government healthcare programs. We currently provide clinical laboratory services in the administration of COVID-19 to tests to employees pursuant to a CLIA Certificate of Waiver. To the extent that our employee testing services were reimbursed by Medicare or Medicaid or to the extent that our role in providing testing services to other entities expanded in the future, the Stark Law could be applicable.

Open Payments. The federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments and other "transfers of value" to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and requires applicable manufacturers to report annually ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information and transfers of value provided (beginning in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives. Failure to submit timely, accurate and complete reports may result in substantial monetary penalties. We are or will be subject to the Open Payments Program and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Eliminating Kickbacks in Recovery Act of 2018. The federal Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). The full scope of such law is uncertain and is subject to a variety of interpretations.

European Fraud and Abuse Laws

In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, a bribe occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act of 1977, or the FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring them to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

U.S. Centers for Medicare and Medicaid Services

Medicare is a federal program administered by CMS through Medicare Administrative Contractors, or MACs. Available to people age 65 or over, and certain other people, Medicare provides, among other things, healthcare benefits that cover, within prescribed limits, the major costs of most medically necessary care for such people, subject to certain deductibles and copayments.

CMS has established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. The reimbursement rate for certain services, including clinical laboratory services, is established under fee schedules that are developed and periodically updated pursuant to specific statutory or regulatory provisions. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our Cue Health Monitoring System and our current and future tests (once approved) could have a material effect on our performance.

CMS also administers the Medicaid program, a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy people. State participation in Medicaid is optional, and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement vary from state to state and is subject to each state's budget restraints. Changes to the availability of coverage, method or level of reimbursement for relevant procedures may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

All CMS programs are subject to statutory and regulatory changes, retroactive and prospective rate adjustments, administrative rulings, interpretations of policy, intermediary determinations, and government funding restrictions, all of which may materially increase or decrease the rate of program payments to healthcare facilities and other healthcare providers.

U.S. Health Reform

Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products once approved. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our Cue Health Monitoring System and any of our current or future tests profitably once approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our Cue Health Monitoring System and any of our current or future tests once approved. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our Cue Health Monitoring System and our current and future tests once approved.

By way of example, the U.S. federal and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), which, among other things, includes changes to the coverage and payment for products under government healthcare programs.

Since enactment of the ACA, there have been, and continue to be, numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On June 17, 2021, the Supreme Court held that the states and individuals that brought the lawsuit challenging the ACA's individual mandate do not have standing to challenge the law. The Supreme Court

did not reach the merits of the challenge, but the decision ends the case. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden Administration will impact the ACA.

Environmental, Health and Safety Regulations

We are subject to various federal, state, local, and foreign environmental, health and safety laws and regulations and permitting and licensing requirements. Such laws include those governing laboratory practices, the generation, storage, use, manufacture, handling, transportation, treatment, remediation, release and disposal of, and exposure to, hazardous materials and wastes and worker health and safety. Our operations involve the generation, use, storage and disposal of hazardous materials, and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations or permitting or licensing requirements cannot be eliminated. In particular, the introduction of our COVID-19 test requires that we maintain compliance with applicable and evolving federal and state laws and regulations relating to COVID-19, including the generation, use, storage, and disposal of testing materials and agents. agents. To date, compliance with environmental laws and regulations has not had a material effect on our business.

Legal Proceedings

From time to time, we are or may become involved in legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

In February 2018, the staff of the U.S. Securities and Exchange Commission's Division of Enforcement issued a subpoena to us requesting certain documents and information. The SEC's subpoena called for the production of documents and information, including documents and information related to one of our prior private financing rounds. We have been cooperating fully with the SEC's investigation. At this time, however, we cannot predict the outcome of this investigation as to us or our officers, nor can we predict the timing associated with any such conclusion or resolution. Based on information currently known to us, we do not believe the SEC's investigation will have a material adverse effect on our business, financial condition or results of operations. However, we cannot assure you that we will not be required to devote significant time or resources to resolving the SEC investigation, or that the ultimate resolution of the investigation will not have a material adverse effect on our business, financial condition or results of operations.

We are not currently a party to any other legal proceedings that we believe may have a material adverse effect on our business, financial condition or results of operations.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information concerning our executive officers and directors as of the effective time of the registration statement of which this prospectus forms a part:

Name	Age	Position
Executive Officers and Employee Directors		
Ayub Khattak	36	President, Chief Executive Officer, Director, Chairman of the Board and Co-Founder
Chris Achar	36	Chief Strategy Officer and Director
John Gallagher	48	Chief Financial Officer
Erica Palsis	36	General Counsel
Clint Sever	36	Chief Product Officer and Co-Founder
Non-Employee Directors		
Joanne Bradford(2)(3)	58	Director
Xiangmin "Min" Cui(2)	53	Director
Carole Faig(1)	59	Director
Maria Martinez(1)(2)(3)	64	Director
Scott Stanford(1)(3)	51	Director

(1) Member of the Audit Committee.
(2) Member of the Compensation Committee.
(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers and Employee Directors

Ayub Khattak. Mr. Khattak is the co-founder of our company and has served as our President and Chief Executive Officer and member of our board of directors since January 2010. He holds a B.S. in mathematics from the University of California, Los Angeles. We believe Mr. Khattak is qualified to serve as a member of our board of directors based on his experience in the healthcare technology industry and his extensive knowledge of our company.

Chris Achar. Mr. Achar has served as a member of our board of directors since May 2018 and was appointed as our Chief Strategy Officer in June 2021. Mr. Achar is the founder of Genzum Life Sciences, Inc., a pharmaceutical company, and has served as its chief executive officer since 2010. Prior, Mr. Achar founded Synergy Ventures, a venture capital company where he serves as a general partner, whose investments include seed stage funding to several medical technology companies including Cue BioPharma Inc. and Provention Bio Inc. Mr. Achar has served as a member of the board of directors of the Network for Teaching Entrepreneurship since 2018. Mr. Achar holds a B.S. in business marketing from California State University and a M.B.A. from Pepperdine University School of Business. We believe Mr. Achar is qualified to serve as a member of our board of directors based on his experience as a healthcare executive and an investor in multiple healthcare and biotech companies.

Clint Sever. Mr. Sever is the co-founder of our company and has served as our Chief Product Officer since January 2010. He holds a B.S. in retail and consumer science from the University of Arizona.

Erica Palsis. Ms. Palsis has served as our General Counsel since February 2021. She was previously General Counsel, Corporate Secretary and Privacy Officer at Livongo Health, Inc. (acquired by Teladoc Health, Inc. in October 2020), a public consumer digital health company, from December 2018 to October 2020 and Vice President and Associate General Counsel from March 2017 to December 2018. Ms. Palsis also served as Corporate Counsel for Allscripts Healthcare Solutions, Inc., a public company providing practice management and electronic health record technology, from May 2014 to March 2017, and Associate Corporate Counsel from March 2010 to May 2014. Ms. Palsis received her B.A. in political science from Loyola University Chicago and J.D. from DePaul University College of Law.

John Gallagher. Mr. Gallagher has served as our Chief Financial Officer since March 2021. Prior to this, Mr. Gallagher served in various capacities at Becton, Dickinson & Company, or BD, a public multinational medical

technology company, including Senior Vice President, Chief Financial Officer, Medical Segment and Treasurer from July 2018 to February 2021, Senior Vice President, Corporate Finance, with responsibility for Financial, Planning & Analysis, Treasury and Chief Accounting Officer/Controller from December 2014 to July 2018 and Vice President, Treasurer from September 2012 to December 2014. Prior to BD, Mr. Gallagher served as Vice President, Financial Planning and Analysis for NBCUniversal Media, LLC, or NBC, an American mass media and entertainment conglomerate, from October 2009 to September 2012. Prior to NBC, Mr. Gallagher served as Assistant Controller, Corporate Treasury for General Electric Company, a public multinational conglomerate, from October 2006 to October 2009. Mr. Gallagher holds a B.S. degree in finance from Clemson University and received his M.B.A. degree from the University of Pittsburgh.

Non-Employee Directors

Joanne Bradford. Ms. Bradford was nominated to our board of directors in August 2021 and joined our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Ms. Bradford currently serves as Chief Growth Officer of Mountain, a connected TV Ad platform. Ms. Bradford has served as President of Honey Science Corp., or Honey, an e-commerce technology platform, since August 2019. Honey was acquired by PayPal in January 2020. Prior to joining Honey, Ms. Bradford was Chief Marketing Officer of Social Finance, Inc., or SoFi, an online personal finance company, from June 2017 to May 2019. She previously served as Chief Operating Officer of SoFi from July 2015 to June 2017. Ms. Bradford served as Head of Partnerships at Pinterest, a social media web and mobile application company, from November 2013 to December 2015. She previously held executive-level roles at the Hearst Corporation, Demand Media, Yahoo!, and Microsoft Corporation. Ms. Bradford serves on the board of directors of private and public companies, Snap Commerce, Katapult and Kahoot! Ms. Bradford has served as a director of Wave App, a small business software company, since October 2018 and OneLogin, a unified access management company, since July 2019 and previously served as a director of Comscore, Inc., a global information and analytics company, from April 2019 until April 2020. Ms. Bradford holds a B.A. in journalism from San Diego State University. We believe Ms. Bradford is qualified to serve on our board of directors due to her over 20 years of experience leading product marketing, business development and programming, as well as building global sales and marketing teams.

Xiangmin "Min" Cui. Dr. Cui has served as a member of our board of directors since June 2020. He is Founder and Managing Director of Decheng Capital, an investment firm focused on life sciences companies. Prior to founding Decheng, Dr. Cui was an investment partner at Bay City Capital, an international life science venture capital firm in San Francisco, California. Dr. Cui was previously director of strategic investment for the Southern Research Institute, a not-for-profit research organization. Prior to that, Dr. Cui co-founded two biopharmaceutical companies, where he led efforts in discovery and development of several key technologies in the fields of oncology, cardiology, infectious and inflammatory diseases. Dr. Cui has served on the board of directors of Alpine Immune Sciences, Inc. (Nasdaq: ALPN), a public clinical-stage biopharmaceutical company, since January 2019. From August 2017 to May 2018, Dr. Cui served as a member of the board of directors of ARMO BioSciences, Inc., a publicly traded immuno-oncology company acquired by Eli Lilly and Company in May 2018. Dr. Cui also serves on the boards of directors of several private companies. Dr. Cui holds a Ph.D. in cancer biology from Stanford University and a B.S. and an M.S. in molecular biology from Peking University. We believe that Dr. Cui's venture capital and management experience in the pharmaceuticals industry provides him with the qualifications and skills necessary to serve as a member of our board of directors.

Carole Faig. Ms. Faig was nominated to our board of directors in August 2021 and joined our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Ms. Faig has more than 38 years of audit and public accounting experience with Ernst & Young LLP, or EY, where she was a partner focused on the healthcare industry. Prior to her retirement from EY in July 2021, Ms. Faig served in a number of leadership roles including U.S. Health Leader and West Region Health and Life Sciences leader, where she managed a $500 million practice. In addition, Ms. Faig has extensive experience as an audit partner serving public and private companies in the health sector. Ms. Faig holds a B.B.A. in accounting from Sam Houston State University and is a certified public accountant. We believe Ms. Faig is qualified to serve on our board of directors due to her extensive experience in the healthcare industry and audit practices.

Maria Martinez. Ms. Martinez was nominated to our board of directors in August 2021 and joined our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. Maria stepped into the role of chief operating officer at Cisco Systems, Inc., or Cisco, in 2021 after having joined Cisco as executive vice president and chief customer experience officer in 2018. Prior to this, Ms. Martinez has

served in a variety of senior executive roles at leading companies such as Salesforce.com, Inc., where she was president of Global Customer Success from March 2016 and chief growth officer from February 2012 to February 2013, and Microsoft Corporation, where she led their global services organization. Ms. Martinez has held additional leadership positions at telecom giants Motorola, Inc. and AT&T Inc., and also served as chief executive officer of Embrace Networks, Inc.

Ms. Martinez's board occupancy has spanned industries across both public and non-profit sectors, including roles at Plantronics, Inc. from September 2015 to April 2018, Declara Inc., and Genesys Works Bay Area. Ms. Martinez actively serves on the board of directors for McKesson Corporation and Silicon Valley Education Foundation, where her experience in leading large, global companies through transformation will help us to advance our mission of empowering people to live their healthiest lives. Ms. Martinez holds a B.S. in electrical engineering from the University of Puerto Rico and a M.S. in electrical engineering from Ohio State University. We believe Ms. Martinez is qualified to serve on our board of directors due to her extensive experience in the technology industry.

Scott Stanford. Mr. Stanford has served as a member of our board of directors since December 2017. Mr. Stanford has served as the co-founder of several companies, including ACME, LLC and its affiliates, a venture capital firm, since February 2013; and Silicon Foundry, a membership-based corporate advisory platform, since February 2013. Prior to these roles, Mr. Stanford served as a managing director at Goldman Sachs from June 2004 until February 2013. Mr. Stanford also serves as a member of the board of directors of several private companies, including Astra Space, Inc., an orbital launch company, since December 2017; Curology, Inc., a direct to consumer prescription skincare company, since September 2015; Luka, Inc., an artificial intelligence and software development company, since April 2016; and BFA Industries (formerly known as ipsy) a personalized beauty commerce company, since September 2015. Mr. Stanford holds an M.B.A. from Harvard Business School. We believe Mr. Stanford is qualified to serve as a member of our board of directors based on his experience as a director of multiple technology and healthcare companies.

Board Composition and Election of Directors

Board Composition

Our board of directors consists of seven members. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Robin Farias-Eisner and Rohan Oza each resigned from our board of directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal.

Our amended and restated certificate of incorporation and bylaws that will become effective immediately prior to the completion of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our amended and restated certificate of incorporation and bylaws will also provide that our directors may be removed only for cause by the affirmative vote of the holders of 75% of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our amended and restated certificate of incorporation and bylaws that will become effective immediately prior to the completion of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Immediately prior to the completion of this offering, the members of the classes will be divided as follows:

- the class I directors will be Xiangmin “Min” Cui and Scott Stanford, and their term will expire at our first annual meeting of stockholders following this offering;
- the class II directors will be Chris Achar and Joanne Bradford, and their term will expire at our second annual meeting of stockholders following this offering; and
- the class III directors will be Carole Faig, Ayub Khattak and Maria Martinez, and their term will expire at our third annual meeting of stockholders following this offering.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See "Description of Capital Stock—Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions."

Director Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In September 2021, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director and director nominee. Based upon information requested from and provided by each director and director nominee concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors and director nominees, with the exception of Ayub Khattak and Chris Achar, is an "independent director" as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate under a charter that has been adopted by our board of directors.

Audit Committee

The members of our audit committee are Carole Faig, Maria Martinez and Scott Stanford. Carole Faig is the chair of the audit committee. Our audit committee's responsibilities will include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;

- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our internal audit function;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Carole Faig is an "audit committee financial expert" as defined in applicable SEC rules and that each of the members of our audit committee possesses the financial sophistication required for audit committee members under Nasdaq rules. We believe that the composition of our audit committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee

The members of our compensation committee are Maria Martinez, Joanne Bradford and Xiangmin "Min" Cui. Maria Martinez is the chair of the compensation committee. Our compensation committee's responsibilities include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Scott Stanford, Joanne Bradford and Maria Martinez. Scott Stanford is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee's responsibilities include:

- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board with respect to our board leadership structure;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing a periodic evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past year has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including operational risks and the other most significant risks we face and our general risk management strategies. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of financial and cybersecurity risks. The nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the code on our website, www.cuehealth.com. In addition, we intend to post on our website all disclosures that are required by law or listing standards concerning any amendments to, or waivers from, any provision of the code.

EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion relates to the compensation of Ayub Khattak, our chief executive officer and Clint Sever, our chief product officer. Mr. Khattak and Mr. Sever are together referred to in this prospectus as our named executive officers.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have begun, and expect to continue in the coming months, to evaluate the need for revisions to our executive compensation program to ensure that our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs.

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)(2)	All Other Compensation	Total ($)
Ayub Khattak *Chief Executive Officer*	2020	$276,923(3)	$250,000	$6,930,773	$ 8,694(4)	$7,466,390
Clint Sever *Chief Product Officer*	2020	$243,235(5)	$233,331	$3,465,387	$257,155(6)	$4,199,108

(1) Except where noted otherwise, the amounts reported in the "Bonus" column reflect discretionary annual cash bonuses earned by each of our named executive officers for their performance, as determined by the board of directors in its sole discretion.

(2) The amounts noted above relate to the purchase of shares of common stock in exchange for promissory notes issued by each of Mr. Khattak and Mr. Sever to us, which notes are partially personally recourse and secured by the shares of common stock purchased therewith. Pursuant to ASC 718, these instruments are treated as grants of stock options for accounting purposes and the amount disclosed is the grant date fair value of these instruments. The assumptions used in calculating the grant date fair value of these instruments are set forth in Note 13 to the audited financial statements included elsewhere in this prospectus.

(3) The amount noted above reflects a $150,000 increase in Mr. Khattak's annual base salary, which took effect as of August 20, 2020.

(4) The amount noted above consists of premiums for medical, vision, dental, and life insurance paid for by us.

(5) The amount noted above reflects a $145,000 increase in Mr. Sever's annual base salary, which took effect August 20, 2020.

(6) The amount noted above consists of compensation resulting from forgiveness of indebtedness of $246,142 and premiums for medical, dental, and life insurance paid for by us.

Narrative to Summary Compensation Table

Base Salary. In 2020, we paid Mr. Khattak an annualized base salary of $225,000 until August 20, 2020, when his annualized base salary was increased by our board of directors to $375,000. In 2020, we paid Mr. Sever an annualized base salary of $205,000 until August 20, 2020, when his annualized base salary was increased by our board of directors to $350,000.

We use base salaries to attract and retain qualified talent and sets salaries at a level that is commensurate with the executive's duties and authorities, contributions, prior experience and sustained performance. We also use base salaries to recognize the experience, skills, knowledge and responsibilities required of all employees, including our named executive officers.

Annual Bonus. Our board of directors may, in its discretion, award bonuses to our named executive officers from time to time. Our employment agreements or offer letters, as applicable, with our named executive officers provide that they will be eligible for annual performance-based bonuses up to a specified percentage of their salary or target dollar amount, subject to approval by our board of directors. Performance-based bonuses, which are calculated as a percentage of base salary, are designed to motivate our employees to achieve annual goals based on our strategic, financial and operating performance objectives. From time to time, our board of directors approved discretionary annual cash bonuses to our named executive officers with respect to their prior year performance.

On August 20, 2020, our compensation committee established that Mr. Khattak and Mr. Sever would be eligible for a bonus of up to 33.33% of their then-current base salary for the fiscal year ended 2020, which was $125,000 in the case

of Mr. Khattak, and $116,667 in the case of Mr. Sever, with the ultimate bonus amount for each to be determined based on our overall financial performance and the level of such executive's contribution to our overall financial performance, as determined at the discretion of the compensation committee after completion of our fiscal year. In recognition of the company's positive 2020 performance, and the particularly notable efforts of our key management despite the ongoing challenges of the COVID-19 pandemic, in December 2020 our board of directors approved cash bonus payouts at two times the target bonus amount for certain of our employees. As a result, our compensation committee approved bonus payments of $250,000 and $233,331 for Mr. Khattak and Mr. Sever, respectively.

Equity Incentives. Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide its executive officers with a strong link to its long-term performance, create an ownership culture and help to align the interests of executive officers and stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain employed during the vesting period. In addition, our board of directors periodically reviews the equity incentive compensation of our executive officers, including our named executive officers, and from time to time may grant equity incentive awards to them in the form of stock options, restricted stock or restricted stock units.

Outstanding Equity Awards at 2020 Fiscal Year-End

The following table sets forth information regarding all outstanding equity awards held by each of our named executive officers as of December 31, 2020:

	Option Awards				Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable[1]	Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)[2]	Market value of shares of stock that have not vested ($)[3]
Ayub Khattak	295,900	—	0.40	07/29/2024	305,517[6]	$ 4,888,272
					2,099,304[7]	$33,588,864
Clint Sever	729,166	104,167[4]	0.48	08/07/2028	55,000[8]	$ 880,000
	989,447	141,350[5]	0.48	08/07/2028	1,075,253[9]	$17,204,048
	295,900	—	0.40	07/29/2024		
	880,000	—	0.20	12/31/2022		
	400,000[10]	—	0.20	07/11/2021		

(1) Of the unvested options reflected in this table, 245,517 options are expected to have vested prior to completion of this offering in accordance with their terms.

(2) Of the unvested shares reflected in this table, 1,282,162 shares are expected to have vested prior to completion of this offering in accordance with their terms.

(3) The market price of common stock is based on the initial public offering price of $16.00 per share.

(4) These options were granted on August 8, 2018 and vest over four years in equal monthly installments, subject to continuous service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested options as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(5) These options were granted on August 8, 2018 and vest over four years, with 25% of the shares having vested on December 31, 2018, and the remainder vesting in equal monthly installments thereafter, subject to continuous service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested options as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(6) These restricted stock awards were granted on August 8, 2018 and vest over four years, with 25% of the shares having vested on December 31, 2018, and the remainder vesting in equal monthly installments thereafter, subject to continuing service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested shares as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(7) These restricted stock awards were granted on July 24, 2020 and vest over four years in equal monthly installments, subject to continuing service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested shares as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(8) These restricted stock awards were granted on August 8, 2018 and vest over four years, with 25% of the shares having vested on December 31, 2018, and the remainder vesting in equal monthly installments thereafter, subject to continuing service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested shares as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(9) These restricted stock awards were granted on July 24, 2020 and vest over four years in equal monthly installments, subject to continuing service. On December 29, 2020, our board of directors approved accelerated vesting of 50% of the unvested shares as of January 1, 2021, effective as of December 29, 2020. The share numbers in the table reflect this acceleration.

(10) On July 8, 2021, our board of directors approved an amendment to this stock option to permit the option to be "net exercised" with respect to the payment of the exercise price and applicable tax withholding.

2021 Co-Founder Equity Awards

Pursuant to the terms of the Khattak employment agreement and the Sever employment agreement (described below under the heading "—Employment Agreements"), effective as of the effective date of the registration statement of which this prospectus forms a part, our board of directors approved the grant of restricted stock unit awards, which we refer to as the Founder RSUs, covering an aggregate of 6,707,320 shares of our common stock to Messrs. Khattak and Sever, whom we refer to as the Co-Founders, of which 3,629,225 Founder RSUs were granted to Mr. Khattak and 3,078,095 Founder RSUs were granted to Mr. Sever.

Our compensation committee and board of directors worked closely with an independent compensation consultant in an effort to design an equity compensation structure for Messrs. Khattak and Sever that would align with our commitment to the long-term interests of our stockholders and require high levels of performance across multiple performance metrics to achieve meaningful value while not encouraging short-term gains through risk-taking, incentivize long-term performance beyond typical market-pay constructs, and be equitable and justifiable to the Co-Founders and our stockholders. As a result, approximately 75% of the Founder RSUs (2,653,114 in the case of Mr. Khattak and 2,279,459 in the case of Mr. Sever) vest based on the satisfaction of both a continued employment condition and the achievement of certain performance goals, which we refer to as the Performance-Vesting RSUs, and approximately 25% (976,111 in the case of Mr. Khattak and 798,636 in the case of Mr. Sever) vest solely based on the satisfaction of a continued employment condition, which we refer to as the Time-Vesting RSUs.

Each Founder RSU that vests in accordance with its terms will be settled with one share of our common stock within 30 days of the applicable vesting date. However, to further encourage the Co-Founders to focus on the long-term success of our business, the Co-Founders must hold any shares that are earned by them pursuant to the Performance-Vesting RSUs (excluding the sale of any shares necessary to satisfy any income or employment tax obligations resulting from the vesting of Performance-Vesting RSUs) for at least one year following the date on which such Performance-Vesting RSU vests. This post-vesting holding period would end before the first anniversary of vesting only in the event of an earlier change in control of our company or a termination of the Founder's employment due to death or disability.

The Time-Vesting RSUs will vest as to 12.5% of the shares of our common stock subject to the award on the six-month anniversary of the grant date and as to an additional 6.25% of the shares of our common stock subject to the award at the end of each three-month period thereafter until the award is fully vested on the fourth anniversary of the grant date, subject, in each case, to the Founder's continuous employment with us. In the event of the termination of the Founder's employment by us without cause or by him with good reason, each as defined in the Founder's employment agreement, the vesting of the Time-Vesting RSUs will accelerate such that the number of Time-Vesting RSUs that, but for such termination, would have otherwise vested in the one-year period following the date of such termination will immediately vest as of the date of such termination. Furthermore, in the event of the termination of the Founder's employment by us without cause or by him with good reason, in either case in the period (i) beginning three months before a change in control (as defined in the Founder's employment agreement), or, in the event we have executed a definitive agreement to effect a change in control as of the date the Founder's employment is terminated by us without cause or by the Founder with good reason, beginning six months before the change in control contemplated by such definitive agreement is consummated, and (ii) ending 24 months following the change in control (which we refer to as the Khattak equity CIC severance period or the Sever equity CIC severance period, as applicable), the vesting of any unvested Time-Vesting RSUs will accelerate in full; provided, however, that if any then-unvested Time-Vesting RSUs are not assumed or substituted for by the resulting or acquiring company (or affiliate of the resulting or acquiring company) in connection with such change in control, the vesting of the Founder's unvested Time-Vesting RSUs will be accelerated in full as of immediately prior to the consummation of the change in control.

The Performance-Vesting RSUs vest upon the achievement of certain stock price performance goals (approximately 70% of the Performance-Vesting RSUs granted to each of the Co-Founders), target revenue performance goals (approximately 20% of the Performance-Vesting RSUs granted to each of the Co-Founders), and a product milestone goal (approximately 10% of the Performance-Vesting RSUs granted to each of the Co-Founders). 1,774,614 of the Performance-Vesting RSUs granted to Mr. Khattak and 1,560,686 of the Performance-Vesting RSUs granted to Mr. Sever, or the Stock Price Target RSUs, are eligible to vest based on our stock price performance over a performance period beginning on the date that is 60 days prior to the date that is nine months after the grant date

and ending on the seven-year anniversary of the grant date, which period we refer to as the Stock Price Performance Period. The Stock Price Target RSUs are divided into seven tranches that are eligible to vest based on the achievement of stock price goals, measured based on an average closing price of our common stock over all trading days within a 60 consecutive calendar day period during the Stock Price Performance Period as set forth below.

	Number of Stock Price Target RSUs Eligible to Vest	
Price Goal	**Khattak**	**Sever**
$30.07	17,615	123,140
$37.13	292,833	239,591
$45.86	292,833	239,591
$56.63	292,833	239,591
$69.94	292,833	239,591
$86.38	292,833	239,591
$106.68	292,834	239,591

There is no linear interpolation between price goals and numbers of Stock Price Target RSUs eligible to vest. The price goals will be adjusted to reflect any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend.

The remainder of the Performance-Vesting RSUs vest as follows:

- 292,833 of the Performance-Vesting RSUs granted to Mr. Khattak and 239,591 of the Performance-Vesting RSUs granted to Mr. Sever, or the FY21 Revenue Target RSUs, are eligible to vest based on the achievement of a specified level of our total revenue (as reported under U.S. generally accepted accounting principles on our financial statement), which we refer to as total revenue, for fiscal year 2021 or, if such total revenue for fiscal year 2021 is not achieved, based on the achievement of a specified level of our aggregate total revenue for fiscal years 2021 and 2022.
- 292,833 of the Performance-Vesting RSUs granted to Mr. Khattak and 239,591 of the Performance-Vesting RSUs granted to Mr. Sever, or the FY22 Revenue Target RSUs, are eligible to vest based on the achievement of a specified level of our total revenue for fiscal year 2022 or, if such total revenue for fiscal year 2022 is not achieved, based on the achievement of a specified level of our aggregate total revenue for fiscal years 2022 and 2023.
- 292,834 of the Performance-Vesting RSUs granted to Mr. Khattak and 239,591 of the Performance-Vesting RSUs granted to Mr. Sever, or the Milestone Target RSUs, are eligible to vest based upon the achievement of a specified product milestone by December 31, 2022. If such milestone is not achieved on or before December 31, 2022 but is achieved during the six-month period beginning on January 1, 2023 and ending on June 30, 2023, 50% of the Milestone Target RSUs will be eligible to vest.

For any tranche of the Performance-Vesting RSUs to vest, except as described below, the Founder generally must remain employed by us as of the date that our compensation committee certifies achievement of the performance goal applicable to that tranche. If the Founder's employment with us terminates, other than a termination by us without cause or by the Founder for good reason, then except as set forth below, any Performance-Vesting RSUs for which the applicable performance objective has not been achieved will be forfeited immediately and automatically to us. If the Founder's employment is terminated by us without cause or by the Founder for good reason other than in connection with a change in control, then:

- 50% of the Stock Price Target RSUs with respect to any price goal that has not been achieved as of the termination date will be retained by the Founder and may be earned after the termination date as follows: (1) if a price goal is achieved within six months of the termination date, 100% of the retained Stock Price Target RSUs associated with the price goal will be earned, (2) if a price goal is achieved after the date that is six months after the termination date but on or prior to the date that is 18 months after the termination date, 50% of the retained Stock Price Target RSUs associated with the price goal will be earned, and (3) if a price goal is achieved after the date that is 18 months after the termination date but on or prior to the date that is 36 months after the termination date, 25% of the retained Stock Price Target RSUs associated with the price goal will be earned;

- 100% of the FY21 Revenue Target RSUs, to the extent then outstanding, will be retained by the Founder and may be earned after the termination date as follows: (1) if the applicable total revenue is achieved within 12 months of the termination date, 100% of the FY21 Revenue Target RSUs will be earned and (2) if the applicable total revenue is achieved more than 12 months following the termination date, 50% of the FY21 Revenue Target RSUs will be earned;
- 100% of the FY22 Revenue Target RSUs, to the extent then outstanding, will be retained by the Founder and may be earned after the termination date as follows: (1) if the applicable total revenue is achieved within 12 months of the termination date, 100% of the FY22 Revenue Target RSUs will be earned and (2) if the applicable total revenue is achieved more than 12 months following the termination date, 50% of the FY22 Revenue Target RSUs will be earned; and
- 100% of the Milestone Target RSUs, to the extent then outstanding, will be retained by the Founder and may be earned after the termination date as follows: (1) if the milestone performance goal is achieved within 12 months of the termination date and on or before December 31, 2022, 100% of the Milestone Target RSUs will be earned, (2) if such goal is achieved within 12 months of the termination date and between January 1, 2023 and June 30, 2023, 50% of the Milestone Target RSUs will be earned, (3) if such goal is achieved more than 12 months following the termination date and on or before December 31, 2022, 50% of the Milestone Target RSUs will be earned, and (4) if such goal is achieved more than 12 months following the termination date and between January 1, 2023 and June 30, 2023, 25% of the Milestone Target RSUs will be earned.

Any Performance-Vesting RSUs that are not retained by the Founder will be forfeited immediately and automatically to us. If the Founder's employment is terminated with cause, (i) all of the Performance-Vesting RSUs will be forfeited immediately and automatically to us, (ii) to the extent any Performance-Vesting RSUs were settled by us prior to the date of termination, any shares that were delivered to the Founder upon such settlement will be automatically forfeited for no consideration, and (iii) to the extent any shares received upon settlement have been sold, the proceeds of such dispositions shall be paid over to us immediately following such termination.

In the event of a change in control of the company:

- Our compensation committee will determine whether any price goals that have not previously been achieved are achieved as a result of the change in control, which determination will be based solely on the price to be paid to our stockholders in connection with the transaction, and the Stock Price Target RSUs with respect to any price goal that is achieved as a result of the change in control will vest immediately prior to the closing of the change in control.
- 50% of any Stock Price Target RSUs have not been earned by the Founder prior to the change in control, taking into account any Stock Price Target RSUs that are earned based on the price paid to our stockholders in the change in control as described above, will be retained by the Founder and converted into time-vested RSUs that vest in equal quarterly installments over the two-year period following the closing of the change in control, subject to the Founder's continued employment on each vesting date. If the Founder's employment is terminated by us without cause or by the Founder for good reason during the period beginning three months before the change in control (or, in the event we have executed a definitive agreement to effect the change in control as of the termination date, the period beginning six months before such change in control) and ending 24 months following the change in control, the retained Stock Price Target RSUs will vest in full as of the date of termination. If the retained Stock Price Target RSUs are not assumed (or substituted for substantially equivalent awards) by the resulting or acquiring company, the retained Stock Price Target RSUs will vest in full immediately prior to the change in control.
- Any FY21 Revenue Target RSUs, FY22 Revenue Target RSUs, or Milestone Target RSUs outstanding immediately prior to the change in control will be eligible to vest immediately prior to the closing of the change in control based on our compensation committee's reasonable and good-faith determination as to the projected level of achievement of the applicable performance objective as of the closing of the change in control. Any such RSUs that do not vest immediately prior to the change in control will be forfeited for no consideration.

Employment Agreements

The following are summaries of employment agreements we have entered into with our executive officers.

Employment Agreement with Ayub Khattak

In connection with Mr. Khattak's continued service following our IPO, we entered into an employment agreement with him dated as of July 8, 2021, which we refer to as the Khattak agreement. Under the Khattak agreement, Mr. Khattak is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason upon written notice.

The Khattak agreement provides that Mr. Khattak is entitled to an annualized base salary of $575,000, and that he is eligible, at our sole discretion, to earn an annual performance bonus of up to 100% of his base salary, or the Khattak post-IPO target bonus; provided that for the 2021 performance year, the amount of any bonus payable to Mr. Khattak shall be based on, for the period beginning on January 1, 2021 and ending on the day prior to the effectiveness of this offering, Mr. Khattak's target bonus and base salary, in each case, as in effect prior to the effectiveness of this offering, and for the period beginning on the effectiveness of this offering and ending on December 31, 2021, the Khattak post-IPO target bonus. The amount of any annual bonus will be determined by our board, or a committee of the board, based on Mr. Khattak's performance and the achievement of individual and corporate goals established by our board following consultation with Mr. Khattak. Except in the event of certain involuntary terminations of Mr. Khattak's employment as described below, Mr. Khattak must be employed on the date that any bonus is approved by the board or the committee in order to earn such bonus. Mr. Khattak is entitled under the Khattak agreement to reimbursement for business expenses pursuant to company policy and the use, which our board may provide in its reasonable discretion, of personal security in connection with required business travel. The Khattak agreement also provides for the award of the Founder RSUs as further described above under the heading "—2021 Co-Founder Equity Awards." In addition, the Khattak agreement provides that we will reimburse Mr. Khattak up to $15,000 for the legal fees incurred by him in connection with the review and negotiation of the Khattak agreement and the Founder RSUs granted to him.

Under the Khattak agreement, in the event of the termination of Mr. Khattak's employment by us without cause or by him with good reason within the period beginning three months prior to and ending 12 months following a change in control, which period we refer to as the Khattak cash CIC severance period and subject to his execution and nonrevocation of a separation agreement and a release of claims in our favor, Mr. Khattak is entitled to (i) continue to receive his annual base salary, payable in equal installments, during the 12-month period following his termination date (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable), (ii) receive an amount equal to 100% of his target bonus for the year in which termination occurs (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable), or if higher, his target bonus immediately prior to the change in control, (iii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of up to 12 months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law, and (iv) if such termination occurs following the end of the applicable performance year but before any annual bonus payable to Mr. Khattak in respect of such performance year is approved by our board, receive an amount equal to any annual performance bonus determined to be payable by our board for such prior performance year. Furthermore, in the event Mr. Khattak's employment is terminated by us without cause or by him with good reason within the Khattak equity CIC severance period, the Khattak agreement provides that Mr. Khattak will be entitled to accelerated vesting of all of his then-unvested equity awards which vest solely based on the passage of time (other than the Founder RSUs, described above under the heading "—2021 Co-Founder Equity Awards", which shall be governed by the terms of the Founder RSU agreements). However, if, in the event of a change in control of our company, Mr. Khattak's then-unvested equity awards (other than the Founder RSUs) that vest based solely on the passage of time are not assumed or substituted for by the resulting or acquiring company (or an affiliate of the resulting or acquiring company), the vesting of such equity awards will be accelerated in full and become immediately exercisable or non-forfeitable as of immediately prior to the consummation of the change in control.

In addition, under the Khattack agreement, in the event that Mr. Khattak's employment is terminated by us without cause or by him with good reason other than within the Khattak cash CIC severance period, and subject to his execution and nonrevocation of a separation agreement and a release of claims in our favor, Mr. Khattak will be entitled to (i) continue to receive his annual base salary, payable in equal installments, during the 12-month period following his termination date (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable), (ii) if such termination occurs following the end of the applicable performance year but before any annual bonus payable to Mr. Khattak in respect of such performance year is approved by our board, receive an amount equal to any annual performance bonus determined to be payable by our board for such prior

performance year, and (iii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of up to 12 months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law.

Employment Agreement with Clint Sever

In connection with Mr. Sever's continued service following our IPO, we entered into an employment agreement with him dated as of July 8, 2021, which we refer to as the Sever agreement. Under the Sever agreement, Mr. Sever is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason upon written notice.

The Sever agreement provides that Mr. Sever is entitled to an annualized base salary of $500,000, and that he is eligible, at our sole discretion, to earn an annual performance bonus of up to 75% of his base salary, or the Sever post- IPO target bonus; provided that for the 2021 performance year, the amount of any bonus payable to Mr. Sever shall be based on, for the period beginning on January 1, 2021 and ending on the day prior to the effectiveness of this offering, Mr. Sever's target bonus and base salary, in each case, as in effect prior to the effectiveness of this offering, and for the period beginning on the effectiveness of this offering and ending on December 31, 2021, the Sever post- IPO target bonus. The amount of any annual bonus will be determined by our board, or a committee of the board, based on Mr. Sever's performance and the achievement of individual and corporate goals established by our board following consultation with Mr. Sever. Except in the event of certain involuntary terminations of Mr. Sever's employment as described below, Mr. Sever must be employed on the date that any bonus is approved by the board or the committee in order to earn such bonus. Mr. Sever is entitled under the Sever agreement to reimbursement for business expenses pursuant to company policy and the use, which our board may provide in its reasonable discretion, of personal security in connection with required business travel. The Sever agreement also provides for the award of the Founder RSUs as further described above under the heading "—2021 Co-Founder Equity Awards." In addition, the Sever agreement provides that we will reimburse Mr. Sever up to $15,000 for the legal fees incurred by him in connection with the review and negotiation of the Sever agreement and the Founder RSUs granted to him.

Under the Sever agreement, in the event of the termination of Mr. Sever's employment by us without cause or by him with good reason within the period beginning three months prior to and ending 12 months following a change in control, which period we refer to as the Sever cash CIC severance period and subject to his execution and nonrevocation of a separation agreement and a release of claims in our favor, Mr. Sever is entitled to (i) continue to receive his annual base salary, payable in equal installments, during the 12-month period following his termination date (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable), (ii) receive an amount equal to 100% of his target bonus for the year in which termination occurs (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable), or if higher, his target bonus immediately prior to the change in control, (iii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of up to 12 months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law, and (iv) if such termination occurs following the end of the applicable performance year but before any annual bonus payable to Mr. Sever in respect of such performance year is approved by our board, receive an amount equal to any annual performance bonus determined to be payable by our board for such prior performance year. Furthermore, in the event Mr. Sever's employment is terminated by us without cause or by him with good reason within the Sever equity CIC severance period, the Sever agreement provides that Mr. Sever will be entitled to accelerated vesting of all of his then-unvested equity awards which vest solely based on the passage of time (other than the Founder RSUs, described above under the heading "—2021 Co-Founder Equity Awards", which shall be governed by the terms of the Founder RSU agreements). However, if, in the event of a change in control of our company, Mr. Sever's then-unvested equity awards (other than the Founder RSUs) that vest based solely on the passage of time are not assumed or substituted for by the resulting or acquiring company (or an affiliate of the resulting or acquiring company), the vesting of such equity awards will be accelerated in full and become immediately exercisable or non-forfeitable as of immediately prior to the consummation of the change in control.

In addition, under the Sever agreement, in the event that Mr. Sever's employment is terminated by us without cause or by him with good reason other than within the Sever cash CIC severance period, and subject to his execution and nonrevocation of a separation agreement and a release of claims in our favor, Mr. Sever is entitled to (i) continue to receive his annual base salary, payable in equal installments, during the 12-month period following his termination date (calculated at a level without taking into account any reduction thereto that triggered good reason, if applicable),

(ii) if such termination occurs following the end of the applicable performance year but before any annual bonus payable to Mr. Sever in respect of such performance year is approved by our board, receive an amount equal to any annual performance bonus determined to be payable by our board for such prior performance year, and (iii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of up to 12 months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law.

Employment Agreement with John Gallagher

In connection with our initial hiring of Mr. Gallagher as our chief financial officer, we entered into an employment agreement with Mr. Gallagher, dated February 23, 2021, which we refer to as the Gallagher agreement. Under the Gallagher agreement, Mr. Gallagher is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason upon written notice.

The Gallagher agreement provides that Mr. Gallagher is entitled to an annualized base salary of $550,000, and that he is eligible, at our sole discretion, to earn an annual performance bonus of up to 50% of his base salary based upon the achievement of corporate and individual goals, as agreed by our board. Additionally, the Gallagher agreement provides for a $400,000 signing bonus, $250,000 of which was paid upon his commencement of employment, and the remaining $150,000 of which will be paid on the six-month anniversary of his commencement of employment, provided he remains employed on such date. The entire signing bonus must be repaid to us in the event that Mr. Gallagher terminates his employment with or without good reason, as defined in the Gallagher agreement, prior to the first anniversary of the commencement of his employment. Mr. Gallagher's agreement also provides for the award of 549,499 restricted stock units, which refer to as the Gallagher RSU Award, which was granted to Mr. Gallagher on March 1, 2021. The Gallagher RSU Award will vest as to 25% of the shares of our common stock subject to the award on the first anniversary of the grant date and as to an additional 6.25% of the shares of our common stock subject to the award at the end of each three-month period thereafter until the award is fully vested on the fourth anniversary of the grant date, provided Mr. Gallagher continues to provide services to us through the relevant vesting dates. Additionally, 25% of the Gallagher RSU Award will vest upon the closing of a going public event, as is defined in the Gallagher agreement and to include this offering, with the remaining unvested portion of the Gallagher RSU Award vesting in equal quarterly installments following the closing of the going public event. Finally, Mr. Gallagher is entitled under the Gallagher agreement to reimbursement for business expenses pursuant to company policy and reimbursement of up to $100,000 in relocation expenses.

Under the Gallagher agreement, Mr. Gallagher is entitled, subject to his execution and nonrevocation of a separation agreement and a general release of claims in our favor, in the event of the termination of his employment by us without cause or by him with good reason, each as defined in the Gallagher agreement, to (i) continue to receive his annual base salary, payable in equal installments, during the nine-month period following his termination date, (ii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of nine months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law, (iii) receive any annual discretionary bonus for the preceding calendar year that our board of directors has approved but not yet paid, (iv) receive an amount equal to a pro rata portion of his target bonus for the year of his termination, based on the number of days he is employed in such year, (v) if such termination occurs prior to the one-year anniversary of the RSU Award grant date, accelerated vesting of the number of shares subject to the RSU Award that would have vested between the grant date and his termination date had the RSU Award vested on a 1/48 per month basis following the grant date, and (v) if such termination occurs within the 60 days prior to or the one year following a change in control of the company (as defined in the Gallagher agreement), the accelerated vesting of 100% of his then-outstanding equity awards which vest solely based on continued service.

Employment Agreement with Erica Palsis

In connection with our initial hiring of Ms. Palsis as our general counsel, we entered into an employment agreement with Ms. Palsis, dated February 1, 2021, which we refer to as the Palsis agreement. Under the Palsis agreement, Ms. Palsis is an at-will employee, and her employment with us can be terminated by her or us at any time and for any reason upon written notice.

The agreement provides that Ms. Palsis is entitled to an annualized base salary of $360,000, and that she is eligible, at our sole discretion, to earn an annual bonus of 33% of her base salary based upon the achievement of

corporate and individual goals, as agreed by the board of directors. Ms. Palsis' agreement also provided for the award of 499,544 restricted stock units, which we refer to as the Palsis RSU Award, which was granted to Ms. Palsis on February 1, 2021. The Palsis RSU Award vests with respect to one-fourth of the shares of our stock subject to the award on each of the first four anniversaries of the grant date, provided Ms. Palsis continues to provide services to us through the relevant vesting dates. The Palsis agreement also provides for our reimbursement of her business expenses pursuant to company policy.

Under the Palsis agreement, Ms. Palsis is entitled, subject to her execution and nonrevocation of a separation agreement and a general release of claims in our favor, in the event of the termination of her employment by us without cause or by Ms. Palsis with good reason, each as defined in the Palsis agreement, to: (i) continue to receive her annual base salary, payable in equal installments, during the nine-month period following her termination date, (ii) our payment of COBRA premiums for health benefit coverage on her behalf, for a period of nine months following her termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law, (iii) receive any annual discretionary bonus for the preceding calendar year that our board has approved but not yet paid, (iv) if such termination occurs prior to the one-year anniversary of the RSU Award grant date, accelerated vesting of the number of shares subject to the RSU Award that would have vested between the grant date and her termination date had the RSU Award vested on a 1/48 per month basis following the grant date, and (v) if such termination occurs within the 60 days prior to or the one year following a change in control of the company (as defined in the Palsis agreement), accelerated vesting of 100% of her then-outstanding equity awards which vest solely based on continued service.

Employment Agreement with Chris Achar

In connection with the appointment of Mr. Achar as our chief strategy officer, we entered into an employment agreement, with him effective July 8, 2021, which we refer to as the Achar agreement. Under the Achar agreement, Mr. Achar is an at-will employee, and his employment with us can be terminated by him or us at any time and for any reason upon written notice.

The agreement provides that Mr. Achar is entitled to an annualized base salary of $400,000, and that he is eligible, at our sole discretion, to earn an annual bonus of 40% of his base salary based upon the achievement of corporate and individual goals, as agreed by the board of directors. Mr. Achar's agreement also provides for the award, subject to board approval, of 1,388,246 restricted stock units, which we refer to as the Achar RSU Award, which was granted to Mr. Achar effective immediately prior to the commencement of trading of our common stock on the Nasdaq Stock Market. The Achar RSU Award vests with respect to one-fourth of the shares of our stock subject to the award on each of the first four anniversaries of the grant date, provided Mr. Achar continues to provide services to us through the relevant vesting dates. The Achar agreement also provides for our reimbursement of his business expenses pursuant to company policy.

Under the Achar agreement, Mr. Achar is entitled, subject to his execution and nonrevocation of a separation agreement and a general release of claims in our favor, in the event of the termination of his employment by us without cause or by Mr. Achar with good reason, each as defined in the Achar agreement, to: (i) continue to receive his annual base salary, payable in equal installments, during the nine-month period following his termination date, (ii) our payment of COBRA premiums for health benefit coverage on his behalf, for a period of nine months following his termination date, at the same rate as we pay for active employees, subject to applicable COBRA terms and in compliance with applicable non-discrimination or other requirements under the law, (iii) receive any annual discretionary bonus for the preceding calendar year that our board has approved but not yet paid, (iv) if such termination occurs prior to the one-year anniversary of the Achar RSU Award grant date, accelerated vesting of the number of shares subject to the Achar RSU Award that would have vested between the grant date and his termination date had the Archar RSU Award vested on a 1/48 per month basis following the grant date, and (v) if such termination occurs within the 60 days prior to or the one year following a change in control of the company (as defined in the Achar agreement), accelerated vesting of 100% of his then-outstanding equity awards which vest solely based on continued service.

Employee Benefits and Perquisites

Our named executive officers participate in employee benefit programs available to its employees generally, including a tax-qualified 401(k) plan. We did not maintain any executive-specific benefit of perquisite programs in 2020.

Equity Incentive Plans

In this section, we describe our Amended and Restated 2014 Equity Incentive Plan, as amended, which we refer to as the 2014 Plan, our 2021 Stock Incentive Plan, which we refer to as the 2021 Plan and our 2021 Employee Stock Purchase Plan, which we refer to as the 2021 ESPP. Prior to this offering, we granted awards to eligible participants under our 2014 Plan. Following the effectiveness of the 2021 Plan, no additional awards will be granted under the 2014 Plan and we expect to grant awards to eligible participants from time to time only under the 2021 Plan.

Amended and Restated 2014 Equity Incentive Plan, as amended

Our 2014 Plan was initially approved by our board of directors and stockholders in August 2014 was subsequently amended and restated in December 2017, and further amended in April 2018, September 2018, June 2020 and January 2021. The 2014 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, performance shares, awards of restricted stock and awards of restricted stock units. Officers and other employees, non-employee directors, consultants and advisors of Cue and its affiliates are eligible to receive awards under the 2014 Plan; however, incentive stock options may only be granted to us or our subsidiaries' employees. Pursuant to the terms of the 2014 Plan, our board of directors (or a committee delegated by our board of directors or one or more officers to whom our board of directors has delegated authority) administers the plan and, subject to the terms of the 2014 Plan, selects:

- the participants to receive awards;
- the type or types of awards to be granted to each participant;
- the number of shares of common stock with respect to which an award relates;
- the terms and conditions of any award.

Awards may be granted alone or in addition to, in tandem with, or in substitution for any other award granted under the 2014 Plan (or any other award granted under another plan of ours or an affiliate of us). The exercise price per share of any stock options granted under the 2014 Plan may not be less than the fair market value, as determined by our board of directors, of a share of common stock on the date of the grant unless the option is not an incentive stock option and complies with Section 409A of the Internal Revenue Code of 1986, as amended, which we refer to as the Code. We may, but are not required, to purchase shares acquired by a participant under the 2014 Plan upon the occurrence of (i) a participant's termination of employment or service or (ii) the issuance of shares following the participant's termination of employment or service pursuant to the terms of an award, such as upon the exercise of an option following termination of employment. The purchase price for the shares subject to repurchase is the fair market value of the shares on the date of the event triggering our right to purchase and may be paid by us in whole or in part with cash, provided that if we do not elect to pay the entire purchase price in cash, we must, at a minimum, pay the participant at least 10% of the purchase price in cash and deliver the participant a promissory note with a principal amount equal to the remainder of the purchase price, on the terms set forth in the 2014 Plan.

Subject to adjustment in the event of certain changes in our capitalization (as described below), the maximum number of shares of common stock authorized for issuance under the 2014 Plan is 22,399,691 shares, all of which may be issued as incentive stock options. Our board of directors may amend, suspend, discontinue or terminate the 2014 Plan at any time, except that stockholder approval is required to (i) materially increase the maximum number of shares authorized for issuance (except as permitted upon certain changes in our capitalization, as described below), (ii) to comply with applicable law, or (iii) for any amendment that would diminish the 2014 Plan's protections relating to certain repricings of options and stock appreciation rights.

Effect of Certain Changes in Capitalization

If we are involved in a merger or other transaction in which our shares of common stock or other securities are changed or exchanged; we subdivide or combine our shares of common stock or other securities or we declare a dividend payable in shares of common stock, other securities or other property; we effect a cash dividend that exceeds, on a per share basis, 10% of the fair market value, as determined by the board, of a share at the time the dividend is declared or we effect any other dividend or other distribution on shares of our common stock or other securities in the form of cash, or a repurchase of our shares of common stock or other securities, that our board of directors determines by resolution is special or extraordinary or that is in connection with a transaction that is a recapitalization or reorganization; we undergo a recapitalization, combination, reclassification or other distribution of

our shares of common stock without receipt of consideration by us; or any other event occurs that in the judgment of our board of directors necessitates an adjustment to prevent dilution or enlargement of benefits or potential benefits intended to be made available under the 2014 Plan, our board of directors is required to adjust, in a manner it may deem to be equitable, any or all of:

- the number and type of shares of common stock subject to the 2014 Plan, including the number and type of shares of common stock that may be issued pursuant to incentive stock options;
- the number and types of shares of common stock subject to outstanding awards;
- the grant, purchase, or exercise price with respect to any award; and
- the performance goals established under any award.

Our board of directors may also make a provision for a cash payment, in an amount determined by our board, to the holder of an outstanding award in exchange for the cancellation of all or a portion of the award, without the consent of the holder of the award, effective at such time as may be specified by our board. Any such adjustment to an award that is exempt from Section 409A of the Code must be made in a manner that ensures the award remains exempt from Section 409A of the Code and any such adjustment to an award that is subject to Section 409A of the Code must be made in a manner that complies with Section 409A of the Code. No such adjustment may be made to incentive stock options to the extent that such authority would cause the 2014 Plan to violate Section 422(b) of the Code.

In the event of any reorganization, merger, consolidation, combination or other similar corporate transaction or event, whether or not such event constitutes a change of control (as defined in the 2014 Plan), other than any such transaction in which we are the continuing corporation and in which our outstanding common stock is not being converted into or exchanged for different securities, cash or other property, or any combination thereof, our board of directors may substitute, on an equitable basis as the board determines, for each share of common stock then subject to an award, the number and kind of shares of stock, other securities, cash or other property to which holders of common stock are or will be entitled in respect of each share of common stock pursuant to the transaction. In addition, in the case of a stock dividend (other than a stock dividend declared in lieu of an ordinary cash dividend) or subdivision or combination of our shares of common stock (including a reverse stock split), if no action is taken by our board of directors, proportionate adjustments described in the foregoing discussion shall nevertheless automatically be made as of the date of such stock dividend or subdivision or combination of shares of common stock.

Effect of Certain Corporate Transactions

Upon a change of control of Cue, our board of directors may, in its discretion, determine that any or all outstanding awards held by participants who are then in the employ or service of us or our affiliates shall vest or be deemed to have been earned in full (assuming the maximum performance goals provided under such award were met, if applicable). In addition, if the successor or surviving corporation (or its parent) so agrees, all outstanding awards will be assumed, or replaced with the same type of award with similar terms and conditions, by the successor or surviving corporation (or its parent) in the change of control with appropriate adjustments. In such a case, if an award has not vested in full upon the change of control, then, if the participant is terminated without cause (as defined in the 2014 Plan) or as a result of death or disability within one year following the change of control, the award will vest in full on the date of such termination. If the foregoing provisions do not apply, then all outstanding awards will be cancelled as of the date of the change of control in exchange for a payment in cash and/or shares of common stock (which may include shares or other securities of any surviving or successor entity or the purchasing entity or any parent thereof) equal to:

- in the case of an option or stock appreciation right, the excess of the fair market value as determined by our board of directors of the shares of common stock on the date of the change of control covered by the vested portion of the option or stock appreciation right that has not been exercised over the exercise or grant price of such shares under the award (provided that, if such fair market value does not exceed the exercise or grant price, the option or stock appreciation rate will be cancelled for no consideration);
- in the case of restricted stock and restricted stock units, the fair market value of a share on the date of the change of control multiplied by the number of vested shares or units; and

- in the case of performance shares, the fair market value of a share on the date of the change of control multiplied by the number of earned shares.

In the event the holders of a majority of our voting capital stock then outstanding, or the majority stockholders, determine to sell or otherwise dispose of all or substantially all of our assets or 50% or more of our capital stock, in each case in a transaction constituting a change of control, to any of our non-affiliate(s) or any of the majority stockholders, or to cause us to merge with or into or consolidate with any non-affiliate(s) or any of the majority stockholders, or in each case, the Buyer, in a bona fide negotiated transaction, which we refer to as a Sale, participants who have acquired shares pursuant to the 2014 Plan are obligated to and must upon the written request of the majority stockholders, among other things, sell, transfer and deliver, or cause to be sold, transferred and delivered, to the Buyer, some or all of such shares (including for this purpose all of such shares of common stock that presently or as a result of any such transaction may be acquired upon the exercise of an option (following the payment of the exercise price for such option)) on substantially the same terms applicable to the majority stockholders (with appropriate adjustments to reflect the conversion of convertible securities, the redemption of redeemable securities and the exercise of exercisable securities as well as the relative preferences and priorities of preferred stock). These rights terminate as to any shares of common stock upon the earlier of (i) the first sale of shares of common stock to the general public in an initial public offering, or (ii) the occurrence of a change of control in which the successor corporation has equity securities that are publicly traded.

As of June 30, 2021, there were 1,049,043 shares subject to outstanding restricted stock units under the 2014 Plan. In addition, as of June 30, 2021, there were options to purchase 7,921,007 shares of common stock outstanding under the 2014 Plan and 1,138,635 shares of common stock were available for future issuance under the 2014 Plan. No further awards will be made under the 2014 Plan on or after the effectiveness of the registration statement for this offering; however, awards outstanding under the 2014 Plan will continue to be governed by their existing terms.

2021 Stock Incentive Plan

In September 2021, our board of directors adopted and our stockholders approved the 2021 Plan, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of our common stock reserved for issuance under the 2021 Plan is the sum of: (1) 14,173,771 shares; plus (2) the number of shares (up to a maximum of 22,399,691) as is equal to the sum of (x) the number of shares of our common stock reserved for issuance under the 2014 Plan that remained available for grant under the 2014 Plan immediately prior to the effectiveness of the registration statement of which this prospectus forms a part and (y) the number of shares of our common stock subject to outstanding awards under the 2014 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, commencing on January 1, 2022 and continuing for each fiscal year until, and including, January 1, 2031, equal to the lesser of (i) 5% of the number of shares of our common stock outstanding on the first day of such fiscal year and (ii) the number of shares of our common stock determined by our board of directors. Subject to adjustment in the event of a change in capitalization or reorganization, up to 56,695,085 of the shares of our common stock available for issuance under the 2021 Plan may be issued as incentive stock options.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan. Incentive stock options, however, may only be granted to our employees.

Pursuant to the terms of the 2021 Plan, our board of directors (or a committee delegated by our board of directors) administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and

- the number of shares of our common stock subject to and the terms of any stock appreciation rights, restricted stock awards, restricted stock units or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years).

If our board of directors delegates authority to one or more of our officers to grant awards under the 2021 Plan, the officers will have the power to make awards to all of our employees, except officers and executive officers (as such terms are defined in the 2021 plan). Our board of directors will fix the terms of the awards to be granted by any such officer, the maximum number of shares subject to awards that such officer may make, and the time period in which such awards may be granted.

The 2021 Plan contains limits on compensation that may be paid to our non-employee directors. In any calendar year, the maximum aggregate amount of cash and value (calculated based on grant date fair value for financial reporting purposes) of awards granted under the 2021 Plan to an individual non-employee director in his or her capacity as a non-employee director may not exceed $750,000. However, this maximum aggregate amount may not exceed $1,000,000 in any calendar year, for any individual non-employee director in that non-employee director's initial year of service. Fees paid by us on behalf of any non-employee director in connection with regulatory compliance and any amounts paid to a non-employee director as reimbursement of an expense will not count towards this limitation. Our board of directors may make additional exceptions to this limit for individual non-employee directors in extraordinary circumstances, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation. This limitation does not apply to cash or awards granted to a non-employee director in his or her capacity as an advisor or consultant to the Company.

Effect of Certain Changes in Capitalization

Upon the occurrence of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, under the terms of the 2021 Plan, we are required to equitably adjust (or make substitute awards, if applicable), in the manner determined by our board of directors:

- the number and class of securities available under the 2021 Plan, and the number and class of securities available for issuance under the 2021 Plan that may be issued as incentive stock options;
- the share counting rules of the 2021 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and the measurement price of each outstanding stock appreciation right;
- the number of shares subject to, and the repurchase price per share subject to, each outstanding award of restricted stock; and
- the share and per-share related provisions and the purchase price, if any, of each outstanding award of restricted stock units and each outstanding other stock-based award.

Effect of Certain Corporate Transactions

Upon the occurrence of a merger or other reorganization event (as defined in the 2021 Plan), our board of directors may, on such terms as our board determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the 2021 Plan as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- provide that outstanding awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of the reorganization event, and/or that all of the participant's vested but unexercised awards will terminate immediately prior to the consummation of the reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of the notice;

- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon such reorganization event;
- in the event of a reorganization event pursuant to which holders of shares of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award; and/or
- provide that, in connection with our liquidation or dissolution, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings).

Our board of directors is not obligated under the 2021 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than our liquidation or dissolution, our repurchase and other rights with respect to outstanding awards of restricted stock will continue for the benefit of the succeeding company and will, unless our board of directors determines otherwise, apply to the cash, securities, or other property which our common stock was converted into or exchanged for pursuant to the reorganization event in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award. However, the board may provide for the termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or in any other agreement between a participant and us, either initially or by amendment. Upon our liquidation or dissolution, except to the extent specifically provided to the contrary in the restricted stock award agreement or any other agreement between the participant and us, all restrictions and conditions on all restricted stock awards then outstanding will automatically be deemed terminated or satisfied.

At any time, our board of directors may provide that any award under the 2021 Plan will become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part as the case may be.

Except with respect to certain actions requiring stockholder approval under the Code or Nasdaq rules, our board of directors may amend, modify or terminate any outstanding award under the 2021 Plan, including but not limited to, substituting for the award another award of the same or a different type, changing the date of exercise or realization, and converting an incentive stock option to a nonstatutory stock option, subject to certain participant consent requirements. However, unless our stockholders approve such action, the 2021 Plan provides that we may not (except as otherwise permitted in connection with a change in capitalization or reorganization event):

- amend any outstanding stock option or stock appreciation right granted under the 2021 Plan to provide an exercise or measurement price per share that is lower than the then-current exercise or measurement price per share of such outstanding award;
- cancel any outstanding stock option or stock appreciation right (whether or not granted under the 2021 Plan) and grant a new award under the 2021 Plan in substitution for the cancelled award (other than substitute awards permitted in connection with a merger or consolidation of an entity with us or our acquisition of property or stock of another entity) covering the same or a different number of shares of our common stock and having an exercise or measurement price per share lower than the then-current exercise or measurement price per share of the cancelled award;
- cancel in exchange for a cash payment any outstanding option or stock appreciation right with an exercise or measurement price per share above the then-current fair market value of our common stock (valued in the manner determined by (or in the manner approved by) our board of directors); or
- take any other action that constitutes a “repricing” within the meaning of Nasdaq rules or rules of any other exchange or marketplace on which our common stock is listed or traded.

No award may be granted under the 2021 Plan on or after the date that is ten years following the effectiveness of the registration statement related to this offering. Our board of directors may amend, suspend or terminate the 2021 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

2021 Employee Stock Purchase Plan

In September 2021, our board of directors adopted and our stockholders approved the 2021 ESPP, which became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The 2021 ESPP will be administered by our board of directors or by a committee appointed by our board of directors. The 2021 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 2,834,754 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2021 ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2022 and continuing until, and including, January 1, 2032, in an amount equal to the lowest of (i) 8,504,263 shares of our common stock, (ii) 1% of the number of shares of our common stock outstanding on such date and (iii) a number of shares of our common stock determined by our board of directors.

All of our employees and employees of any designated subsidiary, as defined in the 2021 ESPP, are eligible to participate in the 2021 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year;
- such person has been employed by us or by a designated subsidiary for at least three months prior to enrolling in the 2021 ESPP; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2021 ESPP.

We retain the discretion to determine which eligible employees may participate in an offering under applicable regulations.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2021 ESPP beginning at such time and on such dates as our board of directors may determine, or on the first business day thereafter. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors or a committee designated by the board of directors may, at its discretion, choose a different period of not more than 12 months for offerings.

On each offering commencement date, each participant will be granted an option to purchase, on the last business day of the offering period, up to a number of shares of our common stock determined by multiplying $2,083 by the number of full months in the offering period and dividing that product by the closing price of our common stock on the first day of the offering period. No employee may be granted an option under the 2021 ESPP that permits the employee's rights to purchase shares under the 2021 ESPP and any other employee stock purchase plan of ours or of any of our subsidiaries to accrue at a rate that exceeds $25,000 of the fair market value of our common stock (determined as of the first day of each offering period) for each calendar year in which the option is outstanding. In addition, no employee may purchase shares of our common stock under the 2021 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

On the commencement date of each offering period, each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2021 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2021 ESPP, the purchase price will be determined by our board of directors or the committee for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors or the committee does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

An employee may at any time prior to the close of business on the fifteenth business day (or such other number of days as is determined by us) prior to the end of the offering period, and for any reason, permanently withdraw from participating in the offering and permanently withdraw the balance accumulated in the employee's account. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be taken and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the extent determined by our board of directors or a committee thereof to the number and class of securities available under the 2021 ESPP, the share limitations under the 2021 ESPP, and the purchase price for an offering period under the 2021 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a merger or other reorganization event, as defined in the 2021 ESPP, our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2021 ESPP on such terms as our board of directors or committee thereof determines:

- provide that options will be assumed, or substantially equivalent options will be substituted, by the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by our board of directors or committee thereof in such notice, which date will not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date; and/or
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the cash payment for each share surrendered in the reorganization event is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2021 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or provide that, in connection with our liquidation or dissolution, options will convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2021 ESPP or any portion of the 2021 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the 2021 ESPP to fail to comply with Section 423 of the Code. The 2021 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees, including our named executive officers. The plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the 401(k) plan, and income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan (except in the case of contributions under the 401(k) plan designated as Roth contributions). Under the 401(k) plan, each employee

is fully vested in his or her deferred salary contributions and our discretionary match. Employee contributions are held and invested by the plan's trustee as directed by participants. The 401(k) plan provides us with the discretion to match employee contributions, but to date we have not provided any employer matching contributions.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with all of our executive officers and directors. These indemnification agreements require us, among other things, to indemnify each such executive officer or director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our executive officers or directors.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend or terminate the plan when not in possession of material, nonpublic information. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Director Compensation

The table below shows all compensation paid to our non-employee directors during the year ended December 31, 2020.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Chris Achar(1)	—	—	—	—	—
Xiangmin “Min” Cui	—	—	—	—	—
Robin Farias-Eisner(2)	—	—	—	—	—
Rohan Oza(3)	—	—	—	—	—
Scott Stanford	—	—	—	—	—
Asish Xavier(4)	—	—	—	—	—

(1) In July 2021, Mr. Achar entered into an employment agreement with the Company, at which time he became an employee director of the Company.

(2) Dr. Farias-Eisner resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(3) Mr. Oza resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(4) Dr. Xavier resigned from our board of directors in April 2021.

We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

Mr. Khattak, one of our directors who also serves as our chief executive officer, does not receive any additional compensation for his service as a director. Mr. Khattak is one of our named executive officers and, accordingly, the compensation that we pay to Mr. Khattak is discussed above under “—Summary Compensation Table” and “—Narrative to Summary Compensation Table.” In addition, effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, our board of directors approved the grant of 64,000 fully vested shares of our common stock to each of Dr. Farias-Eisner and Mr. Oza in recognition of their service to us as directors prior to this offering. Each of Dr. Farias-Eisner and Mr. Oza is required to hold the shares received pursuant to this grant for a period of at least one year following the date of grant.

In June 2021, our board of directors approved a director compensation program that became effective on the effective date of the registration statement of which this prospectus forms a part. Under this director compensation program, we will pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee of which the director is a member. The chairman of the board and of each committee will receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director was not serving on our board of directors. The fees paid to each non-employee director for service on the board of directors and for service on each committee of the board of directors of which the director is a member are as follows:

	Member Annual Fee	Chairman Annual Fee
Board of Directors	$50,000	$95,000
Audit Committee	$ 8,000	$20,000
Compensation Committee	$ 5,000	$12,000
Nominating and Corporate Governance Committee	$ 4,000	$10,000

We also will continue to reimburse each of our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which he or she serves.

In addition, under our director compensation program, each non-employee director will receive, upon his or her initial election or appointment to our board of directors following the effective date of the registration statement of which this prospectus forms a part, a grant of restricted stock units under the 2021 Plan with a target value of $300,000. Each of these restricted stock unit grants will vest as to 34% of the shares of our common stock underlying

such grant on the first anniversary of the grant date and an additional 33% of the shares of our common stock underlying such grant at the end of each successive 12-month period following the first anniversary of the grant date until the third anniversary of the grant date, subject to the non-employee director's continued service as a director. Each non-employee director who is elected to our board of directors between June 23, 2021 and the commencement of trading of shares of our common stock on the Nasdaq Stock Market following the effectiveness of our initial public offering was made an initial grant on the terms and conditions described in this paragraph, effective immediately prior to the commencement of trading of shares of our common stock on the Nasdaq Stock Market.

Further, on the date of each annual meeting of our stockholders following the effective date of the registration statement of which this prospectus forms a part, each non-employee director will receive a grant of restricted stock units under the 2021 Plan with a target value of $190,000. Each of these restricted stock unit grants will vest with respect to 100% of the shares of our common stock underlying such grant on the first anniversary of the grant date, subject to the non-employee director’s continued service as a director (unless otherwise provided at the time of grant). The number of restricted stock units subject to the restricted stock unit grants made to our non-employee directors will be consistent with our practice for determining the number of restricted stock units granted to our employees. All restricted stock units granted to our non-employee directors under our director compensation program will vest in full upon a change in control.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since January 1, 2018, we have engaged in the following transactions in which the amounts involved exceeded $120,000 and any of our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Convertible Note Financing

In May 2020, we issued a convertible promissory note in the aggregate principal amount of $0.5 million to Johnson & Johnson Innovation – JJDC, Inc., or JJDC. This note, which we refer to as the JJDC Note, accrued interest at a rate of 3% per annum. On June 1, 2020, all principal and accrued but unpaid interest under the JJDC Note was converted into 155,571 shares of Cue Health's Series C-2 redeemable convertible preferred stock. Vijay Murthy, a former member of our board of directors, is a former principal at JJDC, and Asish Xavier, a former member of our board of directors, is a principal at JJDC.

In May 2021, we issued and sold Convertible Notes in the aggregate principal amount of $235.5 million in a private placement with net proceeds of $229.5 million. Interest will accrue on the Convertible Notes at a simple rate of 3% per annum. Unless earlier converted immediately prior to the closing of this offering or certain other transactions, the Convertible Notes and any unpaid accrued interest will become due in May 2023. The Convertible Notes will automatically convert into 18,611,914 shares of our common stock immediately prior to the closing of this offering based on accrued interest through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share.

The following table sets forth the aggregate principal amounts of Convertible Notes that we issued to certain of our 5% stockholders and their affiliates and certain affiliates of members of our board of directors:

Purchaser[1]	Principal Amount of Convertible Notes
Decheng Capital China Life Sciences USD Fund III, L.P.[2]	$10,000,000
Funds managed by ACME, LLC and affiliates[3]	4,696,970
JJDC[4]	7,000,000

(1) See "Principal Stockholders" for additional information about shares held by these entities.

(2) Xiangmin "Min" Cui, a member of our board of directors, is the managing director and founder of Decheng Capital China Life Sciences USD Fund III, L.P

(3) Funds managed by ACME, LLC and affiliates are Sherpa Ventures Fund, LP and Sherpa Ventures Fund II, LP, collectively "ACME Capital." Scott Stanford, a member of our board of directors, is a member of, and has a financial interest in ACME Capital.

(4) Vijay Murthy, a former member of our board of directors, is a former principal at JJDC, and Asish Xavier, a former member of our board of directors, is a principal of JJDC.

Agreements with Janssen Pharmaceuticals

In December 2015, we entered into a development, marketing and distribution agreement with Janssen Pharmaceuticals, Inc., or Janssen, pursuant to which Janssen has agreed to provide us funding for the development of our HIV Test Cartridge and Sample Wand in exchange for the right to market and distribute our HIV Test Cartridges and Sample Wands in the future. In the years ended December 31, 2018, 2019, and 2020, we did not receive any payments pursuant to this development, marketing, and distribution agreement. In August 2019, we entered into a research collaboration agreement with Janssen, pursuant to which Janssen has agreed to provide us funding for the development of our respiratory syncytial virus (RSV) Test Kit in exchange for the right to market and distribute our Cue Reader and our multiplexed respiratory diagnostic Test Kit. In the years ended December 31, 2019 and 2020, we received $350,000 and $0, respectively, in payments pursuant to this agreement. In September 2020, we entered into two (2) purchase agreements with Janssen, pursuant to which Janssen purchased our Cue Readers, COVID-19 Test Kits, and Cue Control Swab Packs. In the year ended December 2020, we received $134,390 in payments pursuant to such purchase agreements. Janssen is an affiliate of Johnson & Johnson and JJDC. Vijay Murthy, a former member of our board of directors, is a former principal at JJDC, and Asish Xavier, a former member of our board of directors, is a principal at JJDC.

Promissory Notes and Restricted Stock Purchase Agreements with Executives

In September 2018, we issued 2,444,130 shares of common stock to Mr. Khattak, our Chief Executive Officer and a member of our board of directors, and 480,000 shares of common stock to Mr. Sever, our Chief Product Officer, at a price of $0.48 per share. The shares were issued pursuant to restricted stock purchase agreements with Mr. Khattak and Mr. Sever in exchange for promissory notes totaling $1.2 million and $0.2 million, respectively, to finance the purchase of the shares. Mr. Khattak pledged 2,444,130 shares of vested common stock, as well as the restricted stock purchased with the promissory note, as collateral. Mr. Sever pledged 480,000 shares of vested common stock, as well as the restricted stock purchased with the promissory note, as collateral. The promissory notes bear interest payable annually on each July 1 at a rate equal to 3.06% per year. The promissory notes may be prepaid in full or in part at any time without premium or penalty and are due in September 2028. As described below, all promissory notes between the Company and Mr. Khattak and Mr. Sever have been forgiven.

In July 2020, we issued 4,915,442 shares of common stock to Mr. Khattak, our Chief Executive Officer and a member of our board of directors, and 2,457,721 shares of common stock to Mr. Sever, our Chief Product Officer, at a price of $1.41 per share. The shares were issued pursuant to restricted stock purchase agreements with Mr. Khattak and Mr. Sever in exchange for partially recourse promissory notes totaling $6.9 million and $3.5 million, respectively, to finance the purchase of the shares. Mr. Khattak pledged the restricted stock purchased with the promissory note, as collateral. Mr. Sever pledged the restricted stock purchased with the promissory note, as collateral. The promissory notes bear interest payable annually on each July 1 at a rate equal to 1.17% per year. The promissory notes may be prepaid in full or in part at any time without premium or penalty and are due in July 2030, or earlier upon certain change in control events. As described below, all promissory notes between the Company and Mr. Khattak and Mr. Sever have been forgiven.

In December 2020, our board of directors canceled and forgave $0.2 million in principal and accrued interest under the September 2018 promissory note by and between us and Mr. Sever, or the 2018 Sever Note, and released a total of 960,000 shares of common stock held by Mr. Sever that had been pledged as collateral in connection with the 2018 Sever Note.

In September 2021, our board of directors canceled and forgave $8.3 million in principal and accrued interest, comprised of $1.3 million under the September 2018 promissory note, or the 2018 Khattak Note, and $7.0 million under the July 2020 promissory note, or the 2020 Khattak Note, in each case by and between us and Mr. Khattak, and released a total of 4,888,260 shares of common stock held by Mr. Khattak that had been pledged as collateral in connection with the 2018 Khattak Note and a total of 4,915,442 shares of common stock held by Mr. Khattak that had been pledged as collateral in connection with the 2020 Khattak Note. In September 2021, our board of directors canceled and forgave $3.5 million in principal and accrued interest under the July 2020 promissory note by and between us and Mr. Sever, or the 2020 Sever Note, and released a total of 2,457,721 shares of common stock held by Mr. Sever that had been pledged as collateral in connection with the 2020 Sever Note. Each of Mr. Khattak and Mr. Sever paid the taxes associated with the forgiveness of his promissory note(s).

Series C-1 and C-2 Redeemable Convertible Preferred Stock Financing

In June 2020, we issued and sold an aggregate of 27,308,227 shares of our Series C-1 redeemable convertible preferred stock at a price per share of $3.6619 in cash, for an aggregate purchase price of $100.0 million and issued 1,690,380 shares of our Series C-2 redeemable convertible preferred stock at a price per share of $3.2957 in exchange for an aggregate of $5.6 million in convertible notes issued between May 1, 2020 to May 19, 2020.

The following table sets forth the aggregate numbers of shares of our Series C-1 and Series C-2 redeemable convertible preferred stock that we issued and sold to certain of our 5% stockholders and their affiliates and certain affiliates of members of our board of directors in this transaction and the aggregate amount of consideration for such shares (in millions, except share data):

Purchaser[1]	Series C-1 Redeemable Convertible Preferred Stock Sold for Cash	Cash Purchase Price	Series C-2 Redeemable Convertible Preferred Stock Exchange for Convertible Notes	Principal Amount of Convertible Notes Cancelled Upon Exchange
Decheng Capital China Life Sciences USD Fund III, L.P.[2]	8,192,468	$30.0	—	$—
Madrone Opportunity Fund, L.P.	5,461,645	20.0	—	—

Purchaser[1]	Series C-1 Redeemable Convertible Preferred Stock Sold for Cash	Cash Purchase Price	Series C-2 Redeemable Convertible Preferred Stock Exchange for Convertible Notes	Principal Amount of Convertible Notes Cancelled Upon Exchange
ACME Capital[3]	2,184,658	8.0	—	—
Entities affiliated with Cove Investors I, LLC[4]	273,082	1.0	—	—
JJDC[5]	1,042,136	3.8	155,571	0.5

(1) See "Principal Stockholders" for additional information about shares held by these entities.

(2) Xiangmin "Min" Cui, a member of our board of directors, is the managing director and founder of Decheng Capital China Life Sciences USD Fund III, L.P

(3) Scott Stanford, a member of our board of directors, is a member of, and has a financial interest in ACME Capital.

(4) Robin Farias-Eisner, a member of our board of directors, is an affiliate of Cove Investors I, LP. Dr. Farias-Eisner resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(5) Vijay Murthy, a former member of our board of directors, is a former principal of JJDC, and Ashish Xavier, a former member of our board of directors, is a principal of JJDC.

Other Transactions

In December 2020, Mr. Khattak sold 1,433,691 shares of our common stock to various third-party investors for consideration in the aggregate amount of $22.2 million, 1,616,921 shares of our common stock to Madrone Opportunity Fund, L.P., a holder of more than 5% of our capital stock, for consideration in the aggregate amount of $25.0 million, and 323,385 shares of our common stock to ACME Capital entities who hold more than 5% of our capital stock, for consideration in the aggregate amount of $5 million. We held a right of first refusal and associated notice rights with respect to the shares sold by Mr. Khattak in this transaction, and such rights were waived by us, with approval by the members of our board of directors.

In December 2020, Mr. Sever sold 830,000 shares of our common stock to a third-party investor for consideration in the aggregate amount of $12.8 million. We held a right of first refusal and associated notice rights with respect to the shares sold by Mr. Sever in this transaction, and such rights were waived by us, with approval by the members of our board of directors.

In May 2021, we entered into a consulting agreement with Village Girl LLC, or the Consulting Agreement, effective as of January 1, 2021. Village Girl LLC is an entity affiliated with Chris Achar, a member of our board of directors. Pursuant to the Consulting Agreement, Village Girl LLC agreed to provide consulting services related to, among other things, brand positioning and marketing and sales, in consideration of which we agreed to pay a monthly fee of $30,000 and to reimburse certain expenses. The Consulting Agreement will terminate on September 30, 2021 unless earlier terminated by either us or Village Girl LLC upon 30 days' notice.

For a description of the compensation arrangements that we have with, and various compensation awards we have made with respect to our named executive officers and directors, see "Executive and Director Compensation."

Directed Share Program

At our request, the underwriters have reserved up to 5.0% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers and employees. Shares purchased through this program by our directors, officers and employees will be subject to the 180-day lock-up period under the lock-up agreements described under "Shares Eligible for Future Sale—Lock-up Agreements." See the section titled "Underwriting" for additional information.

Registration Rights

We are a party to an investor rights agreement with the holders of our redeemable convertible preferred stock, including our 5% stockholders and their affiliates and entities affiliated with some of our directors. This investor rights agreement provides these holders the right, subject to certain conditions, beginning six months following the completion of this offering, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing. In addition, these holders also have piggyback registration rights in respect of public offerings we may make for our own account or for other stockholders of our company. Holders of Convertible Notes will also be entitled to registration rights in respect of the common stock issuable upon conversion of the Convertible Notes.

See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Indemnification Agreements

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of our directors and executive officers. These indemnification agreements require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted, effective upon the effectiveness of the registration statement, written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our general counsel. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chairman of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose, and the potential benefits to us, of the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of such entity, that is a participant in the transaction where the related

person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction and the amount involved in the transaction is less than the greater of $200,000 or 5% of the annual gross revenue of the company receiving payment under the transaction; and

- a transaction that is specifically contemplated by provisions of our amended and restated certificate of incorporation or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee's charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of July 31, 2021 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled "Percentage of Shares Beneficially Owned—Before Offering" is based on a total of 29,128,604 shares of our common stock outstanding as of July 31, 2021 and assuming the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock immediately prior to the completion of this offering. The column entitled "Percentage of Shares Beneficially Owned—After Offering" is based on 143,766,583 shares of our common stock assumed to be outstanding after this offering, including (i) the 12,500,000 shares of our common stock that we are selling in this offering, and (ii) 18,611,914 shares of our common stock issuable upon the automatic conversion of the $235.5 million aggregate principal and accrued and unpaid interest on the Convertible Notes based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share upon the closing of this offering, but not including any additional shares issuable upon exercise of outstanding options.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock that an individual has a right to acquire within 60 days after July 31, 2021 are considered outstanding and beneficially owned by the person holding such right for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of each beneficial owner is c/o 4980 Carroll Canyon Rd., Suite 100, San Diego, CA 92121.

The table below excludes any purchases that may be made through our directed share program and any potential purchases in this offering by the beneficial owners identified in the table below.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
5% Stockholders			
ACME Capital[1]	14,869,253	13.20	10.60
Entities affiliated with Cove Investors I, LLC[2]	12,377,254	10.99	8.61
Decheng Capital China Life Sciences USD Fund III, L.P.[3]	8,192,468	7.27	6.25
Madrone Opportunity Fund, L.P.[4]	7,078,566	6.28	4.92
NVGA I, LLC[5]	6,843,692	6.08	4.76
Directors, Director Nominees and Named Executive Officers			
Ayub Khattak[6]	10,907,055	9.66	7.57
Clint Sever[7]	2,211,501	1.96	1.54
Chris Achar[8]	1,589,710	1.41	1.11
Xiangmin "Min" Cui[3]	8,192,468	7.27	6.25
Robin Farias-Eisner[2][9]	12,421,254	11.03	8.64
Rohan Oza[10]	1,104,612	*	2.14
Scott Stanford[1]	14,869,253	13.20	10.60
Joanne Bradford	—	—	—
Carole Faig	—	—	—
Maria Martinez	—	—	—
All current executive officers and directors as a group (9 persons)	51,295,853	45.41	37.78

* Denotes less than 1%.

(1) Consists of (i) 129,354 shares of common stock held by Sherpa Ventures Fund, LP ("ACME I"), (ii) 194,031 shares of common stock held by Sherpa Ventures Fund II, LP ("ACME II"), (iii) 5,450,898 shares of common stock issuable upon conversion of our Series A redeemable convertible preferred stock held by ACME I, (iv) 3,076,224 shares of common stock issuable upon conversion of our shares of Series B redeemable convertible preferred stock held by ACME I, (v) 3,834,088 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by ACME II, (vi) 1,092,329 shares of common stock issuable upon conversion of our Series C-1 redeemable convertible preferred stock held by ACME I, (vii) 1,092,329 shares of common stock issuable upon conversion of our Series C-1 redeemable convertible preferred stock held by ACME II, and (viii) 371,293 shares of common stock issuable upon conversion of our Convertible Notes, based on accrued interest through September 27, 2021, and a 20% discount to the initial public offering price of $16.00 per share, held by ACME II. Sherpa Ventures Fund GP, LLC ("ACME GP I") is the manager of ACME I. SherpaVentures Fund II GP, LLC ("ACME GP II") is the manager of ACME II. Mr. Stanford is a managing member of each of ACME GP I and ACME GP II and may be deemed to have voting and investment power with respect to the shares held by ACME I and ACME II and as a result may be deemed to have beneficial ownership of such shares. Funds managed by ACME, LLC and affiliates of ACME I and ACME II, are collectively defined as "ACME Capital". Scott Stanford is also a member of our board of directors and a member of, and has a financial interest in, ACME Capital. The address for ACME I and ACME II is 800 Market Street, 8th Floor, San Francisco, California 94102.

(2) Consists of (i) 5,655,540 shares of common stock held by Cove Investors I, LLC ("Cove I"), (ii) 1,090,180 shares of common stock issuable upon conversion of our Series A redeemable convertible preferred stock held by Cove Investors I, LLC, (iii) 5,358,452 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by Cove Investors II, LLC ("Cove II") and (iv) 273,082 shares of common stock issuable upon conversion of our Series C-1 redeemable convertible preferred stock held by Cove Investors II, LLC. Dr. Farias-Eisner is a member of Cove I and Cove II. Dr. Farias-Eisner resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. The address for Cove I and Cove II is 865 S. Figueroa Street, Suite 700, Los Angeles, California 90017.

(3) Consists of (i) 8,192,468 shares of common stock issuable upon conversion of our Series C-1 redeemable convertible preferred stock held by Decheng Capital China Life Sciences USD Fund III, L.P. ("Decheng Fund III") and (ii) 787,671 shares of common stock issuable upon conversion of our Convertible Notes, based on accrued interest through September 27, 2021, and a 20% discount to the initial public offering price of $16.00 per share, held by Decheng Capital Global Healthcare Fund (Master), LP ("Decheng Global"). Decheng Capital Management III (Cayman), LLC ("Decheng Capital Management") is the general partner of Decheng Fund III, and Decheng Capital Global Healthcare GP, LLC ("Decheng Global GP") is the general partner of Decheng Global. Dr. Cui is the sole manager of Decheng Capital Management and Decheng Global GP. Dr. Cui may be deemed to have voting and investment power with respect to the shares held by Decheng Fund III and Decheng Global and as a result may be deemed to have beneficial ownership of such shares. Dr. Cui is also a member of our board of directors. The address for Decheng is 3000 Sand Hill Road, Building 2, Suite 110, Menlo Park, California 94025.

(4) Consists of (i) 1,616,921 shares of common stock held by Madrone Opportunity Fund, L.P. ("Madrone") and (ii) 5,461,645 shares of common stock issuable upon conversion of our Series C-1 redeemable convertible preferred stock held by Madrone. Madrone Capital Partners, LLC ("Madrone Capital") is the general partner of Madrone. Thomas Patterson, Jameson McJunkin and Gregory Penner are the managers of Madrone Capital and each may be deemed to have voting and investment power with respect to the shares held by Madrone and as a result may be deemed to have beneficial ownership of such shares. The address for Madrone is 1149 Chestnut St, Suite 200, Menlo Park, California 94025.

(5) Consists of 6,843,692 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by NVGA I, LLC ("NVGA"). TI Manager, LLC ("TI Manager") is the manager of NVGA. TI Manager is managed by its sole member Tarsadia Enterprises, LLC ("Enterprises"). Tushar Patel is the ultimate indirect beneficial owner of Enterprises and may be deemed to have voting and investment power with respect to the shares held by NVGA and as a result may be deemed to have beneficial ownership of such shares. The address for NVGA is c/o Tarsadia Enterprises, LLC, 520 Newport Center Dr., 21st Floor, Newport Beach, CA 92660.

(6) Consists of 10,611,155 shares of our common stock and options to purchase 295,900 shares of our common stock that are exercisable within 60 days of July 31, 2021.

(7) Consists of (i) 187,017 shares of common stock jointly held by Mr. Sever and his spouse and (ii) 2,024,484 shares of our common stock that are exercisable within 60 days of July 31, 2021.

(8) Consists of (i) 69,710 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by Mr. Achar and (ii) 1,488,333 shares of our common stock and 31,667 shares of restricted common stock held by Hlth Wrk LLC as of 60 days from July 31, 2021, due to Mr. Achar's early exercise of his options to purchase shares of our common stock. Mr. Achar is the sole manager of Hlth Wrk LLC and may be deemed to have voting and investment power with respect to the shares held by Hlth Wrk LLC and as a result may be deemed to have beneficial ownership of such shares.

(9) Consists of (i) 16,000 shares of our common stock, and (ii) 28,000 shares of our common stock held in trust by the Robin Farias-Eisner and Therese Farias-Eisner joint trust with rights of survival, or the Farias-Eisner Trust. Dr. Farias-Eisner is the trustee of the Farias-Eisner Trust and may be deemed to indirectly beneficially own such shares. Dr. Farias-Eisner resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(10) Consists of (i) 280,681 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by Mr. Oza, (ii) 545,089 shares of common stock issuable upon conversion of our Series A redeemable convertible preferred stock held by RONO, LLC ("RONO"), (iii) 278,842 shares of common stock issuable upon conversion of our Series B redeemable convertible preferred stock held by RONO and (iv) 1,976,241 shares of common stock issuable upon conversion of our Convertible Notes, based on accrued interest through September 27, 2021, and a 20% discount to the initial public offering price of $16.00 per share, held by Cavu Venture Partners III, L.P. ("Cavu"). Mr. Oza is the managing member of RONO and may be deemed to have voting and investment power with respect to the shares held by RONO and as a result may be deemed to have beneficial ownership of such shares. Mr. Oza is a managing member and co-founder of Cavu and may be deemed to have voting and investment power with respect to the shares held by Cavu and as a result may be deemed to have beneficial ownership of such shares. Mr. Oza resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the bylaws that will become effective immediately prior to the completion of this offering. We will file copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur immediately prior to the completion of this offering.

Immediately prior to the completion of this offering, our authorized capital stock will consist of 500,000,000 shares of our common stock, par value $0.00001 per share, and 50,000,000 shares of our preferred stock, par value $0.00001 per share, all of which preferred stock will be undesignated.

As of June 30, 2021, we had issued and outstanding:

- 29,128,604 shares of common stock held by 60 stockholders of record;
- 8,350,743 shares of our Series A redeemable convertible preferred stock held by 22 stockholders of record, convertible into 8,350,743 shares of our common stock;
- 46,176,715 shares of our Series B redeemable convertible preferred stock held by 36 stockholders of record, convertible into 46,176,715 shares of our common stock;
- 27,308,227 shares of our Series C-1 redeemable convertible preferred stock held by 21 stockholders of record, convertible into 27,308,227 shares of our common stock; and
- 1,690,380 shares of our Series C-2 redeemable convertible preferred stock held by 5 stockholders of record, convertible into 1,690,380 shares of our common stock.

Immediately prior to the completion of this offering, all of the outstanding shares of our redeemable convertible preferred stock will automatically convert into an aggregate of 83,526,065 shares of our common stock and upon the closing of this offering, all of our outstanding $235.5 million in aggregate principal amount of Convertible Notes will convert into 18,611,914 shares of common stock, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third

party from seeking to acquire, a majority of our outstanding voting stock. Immediately prior to the completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Convertible Notes

Please see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Convertible Notes."

Options

As of June 30, 2021, we had options to purchase an aggregate of 9,944,197 shares of our common stock outstanding, with a weighted-average exercise price of $4.93 per share.

Restricted Stock Units

As of June 30, 2021, we had 1,049,043 shares of restricted stock units outstanding.

Warrants

As of June 30, 2021, we had warrants to purchase 48,513 shares of Series A preferred stock outstanding at an exercise price of $0.92 and warrants to purchase 31,369 shares of Series B preferred stock at an exercise price of $1.43 per share and warrants to purchase 75,744 shares of common stock at an exercise price of $0.40 per share.

Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, or the DGCL. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that will own 15% or more of our outstanding voting stock upon the closing of this offering.

Staggered Board; Removal of Directors

Our amended and restated certificate of incorporation and our bylaws to be effective immediately prior to the completion of this offering divide our board of directors into three classes with staggered three-year terms. In addition, our amended and restated certificate of incorporation and our bylaws to be effective immediately prior to the completion of this offering provide that directors may be removed only for cause and only by the affirmative vote of the holders of at least 75% of our shares of capital stock present in person or by proxy and entitled to vote. Under our amended and restated certificate of incorporation and our bylaws to be effective immediately prior to the completion of this offering, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. Furthermore, our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our amended and restated certificate of incorporation and our bylaws to be effective immediately prior to the completion of this offering provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may

not be taken by written action in lieu of a meeting. Our amended and restated certificate of incorporation and our bylaws to be effective immediately prior to the completion of this offering also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our board of directors. In addition, our bylaws to be effective immediately prior to the completion of this offering establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-Majority Voting

The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws to be effective immediately prior to the completion of this offering may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our amended and restated certificate of incorporation described above.

Indemnification Agreements

Our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we intend to enter into indemnification agreements with all of our directors and executive officers prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers.

Exclusive Forum

Our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our amended and restated certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act, the Exchange Act or any other claim for which federal courts have exclusive jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering provides

that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Registration Rights

We have entered into an amended and restated investor rights agreement dated as of June 1, 2020, or the investor rights agreement, with holders of our preferred stock. Beginning 180 days after this offering, holders of a total of 111,434,865 shares of our common stock, including 18,611,914 shares of our common stock that will have been issued pursuant to the conversion of the Convertible Notes upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, will have the right to require us to register these shares under the Securities Act upon demand and in connection with any registration statement that we plan to file, as described below under "—Demand Registration Rights" and "—Incidental Registration Rights." We refer to the shares with these registration rights as registrable securities. After registration pursuant to these rights, the registrable securities will become freely tradable without restriction under the Securities Act. Holders of Convertible Notes will also be entitled to registration rights in respect of the common stock issuable upon conversion of the Convertible Notes.

Demand Registration Rights

Beginning 180 days after the effective date of the registration statement of which this prospectus is a part, subject to specified limitations set forth in the investor rights agreement, at any time, the holders of outstanding registrable securities may demand that we register at least a majority of the registrable securities then outstanding under the Securities Act for purposes of a public offering for which the reasonably anticipated aggregate offering price to the public is at least $20.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

In addition, subject to specified limitations set forth in the investor rights agreement, at any time after we become eligible to file a registration statement on Form S-3, the holders of at least 25% of the then outstanding registrable securities may request that we register their registrable securities on Form S-3 for purposes of a public offering for which the reasonably anticipated aggregate offering price to the public, net of selling expenses, is at least $1.0 million. We are not obligated to file a registration statement pursuant to this provision on more than two occasions in any 12-month period.

Piggyback Registration Rights

If, at any time after the closing of this offering, we propose to register for our own account any of our securities under the Securities Act, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to use our commercially reasonable efforts to register all or a portion of the registrable securities then held by them in that registration.

In the event that any registration in which the holders of registrable securities participate pursuant to our investor rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form and use our reasonable best efforts to facilitate such offering.

Expenses

Pursuant to the investor rights agreement, we are required to pay all registration expenses, including all registration and filing fees, exchange listing fees, printing expenses, fees and expenses $25,000 of one counsel selected by the selling stockholders to represent the selling stockholders, state Blue Sky fees and expenses, and the expense of any special audits incident to or required by any such registration, but excluding underwriting discounts, selling commissions, stock transfer taxes applicable to the sale any registrable securities and the fees and expenses of the selling stockholders' own counsel (other than the counsel selected to represent all selling stockholders). If a registration is withdrawn at the request of the stockholders initiating the registration, then the stockholders will bear the expenses of the registration.

The investor rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Exchange Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "HLTH."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Immediately prior to the completion of this offering, we will have outstanding 143,766,583 shares of our common stock, based on the shares of our common stock that were outstanding on June 30, 2021 and after giving effect to (i) the issuance of 12,500,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares, (ii) the conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 83,526,065 shares of our common stock immediately prior to the completion of this offering, and (iii) the automatic conversion of our outstanding $235.5 million in aggregate principal amount of Convertible Notes into 18,611,914 shares of common stock upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share. Of these shares, all shares sold in this offering will be freely tradable without restriction under the Securities Act of 1933, as amended, or the Securities Act, unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 131,266,583 shares of our common stock will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or 701 under the Securities Act.

Rule 144

In general, under Rule 144 of the Securities Act, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 1,437,666 shares immediately after this offering; and
- the average weekly trading volume in our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 180-day lock-up period described below, approximately 131,266,583 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell these shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding

period and volume limitations, contained in Rule 144. All Rule 701 shares are subject to the 180-day lock-up period described below and will be eligible for sale in accordance with Rule 701 upon expiration of the restrictions set forth in those agreements.

Lock-up Agreements

We, and each of our executive officers and directors and the holders of substantially all of our outstanding securities have agreed that, without the prior written consent of Goldman, Sachs & Co. LLC and Morgan Stanley & Co. LLC, on behalf of the underwriters, we and they will not, among other things and subject to certain limited exceptions, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock beneficially owned (as such term is used in Rule 13d-3 of the Exchange Act) or any other securities so owned convertible into or exercisable or exchangeable for common stock, or make any public announcement of an intention to do any of the foregoing; or
- enter into any hedging, swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled “Underwriting.”

Registration Rights

Beginning 180 days after this offering, the holders of an aggregate of 111,434,865 shares of our common stock, including 18,611,914 shares of our common stock that will have been issued pursuant to the conversion of the Convertible Notes upon the closing of this offering, based on interest accrued through September 27, 2021 and a 20% discount to the initial public offering price of $16.00 per share, will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

Stock Options and Form S-8 Registration Statements

Following the effectiveness of the registration statement of which this prospectus forms a part, we intend to file one or more registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding awards and reserved for future issuance under the 2014 Plan, the 2021 Plan and the 2021 ESPP, as well as outstanding awards granted prior to the adoption of the 2014 Plan. See “Executive Compensation—Stock Option and Other Compensation Plans” for additional information regarding these plans. Accordingly, shares of our common stock registered under such registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder. For purposes of this discussion, the term "non-U.S. holder" means a beneficial owner (other than a partnership or other entity or arrangement treated as a pass-through entity) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons has authority to control all substantial decisions of the trust or if the trust has a valid election in effect to be treated as a U.S. person under applicable U.S. Treasury Regulations.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings, and judicial decisions, as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. We have not requested a ruling from the Internal Revenue Service, or the IRS, with respect to statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will not challenge one or more of the tax consequences described in this prospectus or that any such challenge would not be sustained by a court.

This discussion addresses only non-U.S. holders that hold shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address the alternative minimum tax, the special tax accounting rules under Section 451(b) of the Code, the Medicare tax on net investment income or any aspects of U.S. state, local, or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds" as defined in Section 897(1)(2) of the Code and entities of all of the interests of which are held by qualified foreign pension funds;
- persons that own, or are deemed to own, more than 5% if our capital stock;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security, or other integrated investment; and
- certain U.S. expatriates and former citizens or long-term residents of the United States.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other entities or arrangements that are treated as pass-through entities for U.S. federal

income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her, or its own tax advisor regarding the tax consequences of the purchase, ownership, and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local, and non-U.S. income and other tax considerations of acquiring, holding, and disposing of our common stock in light of their particular situations.

Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Disposition of Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States are generally exempt from the 30% withholding tax if the non-U.S. holder delivers a properly executed IRS Form W-8ECI, stating that the dividends are so connected and satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income is taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

See also the section below entitled "—FATCA" for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Gain on Disposition of Common Stock

Subject to the discussions below under the sections entitled "—Information Reporting and Backup Withholding" and "—FATCA," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code), and if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses, if any; or

- we are, or have been at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter), a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition generally in the same manner as gain that is effectively connected with the conduct of a trade or business in the United States, at the U.S. federal income tax rates applicable to United States persons (as defined in the Code), except that the branch profits tax generally will not apply. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN, W-8BEN-E or W-8ECI (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "— Dividends," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

FATCA

Sections 1471 to 1474 of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a 30% U.S. federal withholding tax on dividends on, and gross proceeds from the sale or other disposition of, our common stock if paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors, or (iii) the foreign entity is otherwise excepted under FATCA.

Withholding under FATCA generally will apply to payments of dividends on our common stock. While under applicable Treasury Regulations and administrative guidance withholding under FATCA would also apply to payments of gross proceeds from a sale or other disposition of our common stock made after December 31, 2018, under proposed U.S. Treasury Regulations, withholding on payments of gross proceeds is not required. Although such

regulations are not final, the preamble to the proposed regulations specifies that taxpayers, including applicable withholding agents, are permitted to rely on such proposed regulations until final regulations are issued.

If withholding under FATCA is required on any payment related to our common stock, investors not otherwise subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) on such payment may be required to seek a refund or credit from the IRS. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock and the entities through which they hold our common stock.

U.S. Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise. Non-U.S. holders are urged to consult their own tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock.

The preceding discussion of material U.S. federal income and estate tax considerations is for prospective investors' information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of purchasing, holding, and disposing of our common stock.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	5,375,000
Morgan Stanley & Co. LLC	4,625,000
Cowen and Company, LLC	1,875,000
BTIG, LLC	625,000
Total	12,500,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,875,000 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 1,875,000 shares from us.

	No Exercise	Full Exercise
Per Share	$ 1.12	$ 1.12
Total	$14,000,000	$16,100,000

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $0.672 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus (such period, the "restricted period"), except with the prior written consent of Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC, not to (i) offer, sell, contract to sell, pledge, grant any option to purchase, loan, hedge, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the SEC a registration statement under the Securities Act relating to, any of our securities that are substantially similar to the shares of common stock in this offering, including but not limited to any options or warrants to purchase shares of common stock or any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or any such substantially similar securities, (ii) enter into any hedging, swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of common stock or any such other securities, whether any such transaction described in clauses (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise (other than the shares of common stock to be sold in this offering or pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date of this prospectus) or (iii) publicly disclose the intention to do any of the foregoing. The restrictions described in the immediately preceding paragraph do not apply to us subject to certain exceptions.

The restrictions described above do not apply to us for certain transactions, including (i) the sale of shares by us to the underwriters in this offering; (ii) the issuance of stock upon the conversion of redeemable convertible preferred stock and convertible promissory notes outstanding on the date of this prospectus in connection with this

offering, provided that any shares of common stock issued upon such conversion will remain subject to a lock-up agreement; (iii) securities issued pursuant to an employee stock option plan, incentive plan, stock plan, dividend reinvestment plan or otherwise pursuant to equity compensation arrangements in place as of the date of this prospectus and as described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iv) the grant of awards pursuant to employee equity based compensation plans, incentive plans, stock plans or other arrangements in place as of the date of this prospectus and as described in this prospectus, that such recipients enter into a lock-up agreement with the underwriters; (v) the filing of a registration statement on Form S-8; and (vi) the issuance of up to 5% of the outstanding shares of our capital stock immediately following the closing of this offering, in acquisitions or other similar strategic transactions, provided that such recipients enter into a lock-up agreement with the underwriters.

The restrictions described above do not apply, subject in certain cases to various conditions, to our directors, officers and securityholders with respect to certain transactions, including:

(a) as a bona fide gift or gifts;

(b) to any member of the securityholder's immediate family or to any trust for the direct or indirect benefit of the securityholder or the immediate family of the securityholder;

(c) by will or other testamentary document or by intestacy;

(d) pursuant to a court order or settlement or other domestic order related to the distribution of assets in connection with the dissolution of a marriage or civil union;

(e) to general or limited partners, members, stockholders, other equity holders or trust beneficiaries of the securityholder or to any investment fund or other entity that controls or manages or serves as investment adviser to, or is under common control or management or shares a common investment adviser with, the securityholder;

(f) in connection with any common stock acquired in this offering (other than any issuer directed shares of common stock purchased in this offering by our officer or director) acquired in open market transactions after the completion of this offering;

(g) to us in connection with the "net" or "cashless" exercise or settlement solely to cover the exercise price and applicable withholding tax obligations in connection with the exercise or settlement of such warrants or stock options, restricted stock units or other equity awards expiring during the restricted period, in each case pursuant to a stock incentive plan, other equity award plan or warrant described in this prospectus (and any transfer to us necessary to generate such amount of cash needed for the payment of withholding tax obligations, and/or payment of estimated taxes, due as a result of such vesting, settlement or exercise whether by means of a "net settlement" or otherwise), provided that if the securityholder is required to file a report reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause and that the shares of common stock received upon exercise of the stock option or warrant or vesting event are subject to the lock-up agreement, and no public filing, report or announcement shall be voluntarily made;

(h) pursuant to a bona fide third-party tender offer, merger, consolidation, business combination, stock purchase or other similar transaction or series of related transactions approved by our board of directors and made to all holders of our capital stock involving a change in control, provided that in the event that such tender offer, merger, consolidation, business combination, stock purchase or transaction or series of related transactions is not completed, the securityholder's securities shall remain subject to the restrictions set forth in the lock-up agreement;

(i) the conversion of outstanding shares of our preferred stock or other securities described in this prospectus and outstanding as of the date of this prospectus into shares of common stock or derivative instruments, as described in this prospectus, provided that the shares of common stock or any derivative instruments received upon conversion shall be subject to the restrictions set forth in the lock-up agreement;

(j) to us pursuant to any contractual arrangement in effect on the date of the lock-up agreement and disclosed in this prospectus that provides for the repurchase of shares of common stock in connection with the termination of the securityholder's employment with or service to us, provided no public filing, report or

announcement reporting a reduction in beneficial ownership of shares of common stock shall be required or shall be voluntarily made during the restricted period within 75 days after the date the securityholder ceases to provide services to us, and after such 75th day, if the securityholder is required to file a report reporting a reduction in beneficial ownership of shares of common stock during the restricted period, the securityholder shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause and no public filing, report or announcement shall be voluntarily made;

(k) with the prior written consent of Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC on behalf of the underwriters;

(l) if the securityholder is a corporation, partnership, limited liability company or other business entity, the corporation, partnership, limited liability company or other business entity may effect a transfer to any other corporation, partnership, limited liability company or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the securityholder; provided, however, that in any such case, it shall be a condition to the transfer that the transferee execute an agreement stating that the transferee is receiving and holding such capital stock subject to the provisions of the lock-up agreement and there shall be no further transfer of such capital stock except in accordance with the lock-up agreement, and provided further that any such transfer shall not involve a disposition for value and no public filing under the Exchange Act, or announcement shall be required or shall be made voluntarily;

(m) the securityholder may receive shares of common stock from us in connection with (i) the exercise of options or other rights granted under a stock incentive plan or other equity award plan, limited only to a plan that is described in this prospectus and (ii) the exercise of warrants, which warrants are described in this prospectus; provided that, in each case, any shares of common stock issued upon exercise of such option, warrant or other rights shall continue to be subject to the restrictions set forth herein until the expiration of the restricted period; provided further, that if the securityholder is required to file a report under Section 16 of the Exchange Act reporting such exercise of options or other rights, the securityholder shall include a statement in such report to the effect that any shares of common stock issued upon exercise of such option or other rights remain subject to the restrictions set forth in the lock-up agreement, and provided further that no filing or other public announcement shall be voluntarily made; and

(n) the securityholder may enter into any plan designed to satisfy the requirements of Rule 10b5-1 (a “10b5-1 Plan”) under the Exchange Act (other than the entry into such a plan in such a manner as to allow the sale of shares of common stock, in each case, within the restricted period); provided, however that, no sale of shares of common stock may be made under such 10b5-1 Plan during the restricted period; and provided further that no public filing, report or announcement regarding the establishment of such plan shall be required or shall be voluntarily made during the restricted period.

Prior to the offering, there has been no public market for the shares. The initial public offering price was negotiated among the company and the representatives. Among the factors considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, were the company’s historical performance, estimates of the business potential and earnings prospects of the company, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “HLTH.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create

a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $6.8 million. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $40,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have in the past provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they have received and will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of ours (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

Affiliates of Goldman Sachs & Co. LLC purchased 829,077 shares of our Series C-1 redeemable convertible preferred stock in our June 2020 Series C-1 redeemable convertible preferred stock financing. These shares of redeemable convertible preferred stock will automatically convert into 829,077 shares of common stock immediately prior to and in connection with the completion of this offering.

Directed Share Program

At our request, the underwriters have reserved up to 5.0% of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers and employees. Shares purchased through this program by our directors, officers and employees will be subject to the 180-day lock-up period under the lock-up agreements described under “Shares Eligible for Future Sale—Lock-up Agreements.” The sales will be made at our direction by Morgan Stanley & Co. LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so

purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the shares reserved for the directed share program.

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided

that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32")

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets

products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority ("DFSA"). This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority ("FINMA") as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended ("CISA"), and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licenseable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from

Switzerland. The securities may solely be offered to "qualified investors," as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended ("CISO"), such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Palo Alto, California. Cooley LLP, San Diego, California is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements as of December 31, 2019 and 2020 and for the years then ended included in this prospectus and in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding our ability to continue as a going concern) appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference to such contract, agreement or document.

The SEC maintains a website, which is located at http://www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus forms a part at the SEC's website. Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. We plan to fulfill our obligations with respect to such requirements by filing periodic reports and other information with the SEC. We intend to furnish our stockholders with annual reports containing financial statements certified by an independent registered public accounting firm. Our website address is www.cuehealth.com.com, and upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Cue Health Inc.
San Diego, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Cue Health Inc. (the "Company") as of December 31, 2019 and 2020, the related statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Notes 2 and 8 of the financial statements, effective January 1, 2020, the Company has changed its method of accounting for leases due to the adoption of Accounting Standards Codification Topic 842, *Leases*.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2019.

San Diego, California

April 19, 2021

Cue Health Inc.
Balance Sheets
(In thousands, except share data)

	December 31,	
	2019	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 14,328	$ 121,578
Restricted cash	—	6,000
Accounts receivable	200	4,168
Inventory	—	36,842
Prepaid expenses	669	13,847
Other current assets	307	1,263
Total current assets	15,504	183,698
Restricted cash, non-current	177	1,677
Property and equipment, net	11,630	103,683
Prepaid rent	—	16,771
Operating lease right-of-use assets	—	8,281
Intangible assets, net	—	2,038
Other non-current assets	50	180
Total assets	$ 27,361	$ 316,328
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,168	$ 23,847
Accrued liabilities	566	8,822
Deferred revenue, current	12	115,747
Deferred rent, current	28	—
Debt, current	2,555	5,434
Operating lease liabilities, current	—	797
Finance lease liabilities, current	422	1,249
Total current liabilities	4,751	155,896
Redeemable convertible preferred stock warrant liabilities	42	1,331
Deferred revenue, net of current portion	—	67,349
Deferred rent, net of current portion	2,729	—
Debt, net of current portion	3,776	—
Operating leases liabilities, net of current portion	—	10,472
Finance lease liabilities, net of current portion	497	1,857
Other non-current liabilities	—	4,500
Total liabilities	11,795	241,405
Commitments and contingencies (Note 16)		
Redeemable Convertible Preferred Stock		
Series A redeemable convertible preferred stock, $0.00001 par value; 8,721,437 shares authorized, 8,350,743 issued and outstanding at December 31, 2019 and 2020; liquidation preference of $7,660 at December 31, 2019 and 2020	7,519	7,519
Series B redeemable convertible preferred stock, $0.00001 par value; 46,213,620 shares authorized, 46,176,715 issued and outstanding at December 31, 2019 and 2020; liquidation preference of $66,240 at December 31, 2019 and 2020	66,186	66,186
Series C-1 redeemable convertible preferred stock; $0.00001 par value; 27,308,229 shares authorized, 27,308,227 issued and outstanding at December 31, 2020 and none authorized, issued and outstanding at December 31, 2019; liquidation preference of $100,000 at December 31, 2020	—	96,436
Series C-2 redeemable convertible preferred stock; $0.00001 par value; 1,690,380 shares authorized, issued and outstanding at December 31, 2020 and none authorized, issued and outstanding at December 31, 2019; liquidation preference of $5,571 at December 31, 2020	—	6,182
Total redeemable convertible preferred stock	73,705	176,323
Stockholders' Deficit		
Common stock, $0.00001 par value; 88,778,540 and 129,030,355 shares authorized, 18,704,118 and 27,995,780 issued and outstanding at December 31, 2019 and 2020, respectively	—	—

Additional paid-in-capital	4,945	9,036
Accumulated deficit	(63,084)	(110,436)
Total stockholders' deficit	(58,139)	(101,400)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 27,361	$ 316,328

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.
STATEMENTS OF OPERATIONS
(In thousands, except share data)

	Year Ended December 31,	
	2019	2020
Revenue		
Product revenue	$ —	$ 15,391
Grant and other revenue	6,626	7,562
Total revenue	6,626	22,953
Operating costs and expenses:		
Cost of product revenue	—	14,951
Sales and marketing	88	714
Research and development	21,405	28,478
General and administrative	5,900	23,936
Total operating costs and expenses	27,393	68,079
Loss from operations	(20,767)	(45,126)
Interest expense	(152)	(984)
Change in fair value of redeemable convertible preferred stock warrants	4	(1,289)
Other income	309	47
Net loss	$ (20,606)	$ (47,352)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.31)	$ (2.90)
Weighted-average number of shares used in computation of net loss per share attributable to common stockholders, basic and diluted	15,760,246	16,315,730

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.
STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2019	8,350,743	$ 7,519	46,176,715	$ 66,186	—	$ —	18,679,868	$ —	$ 4,597	$ (42,478)	$ (37,881)
Exercise of common stock options	—	—	—	—	—	—	24,250	—	12	—	12
Stock-based compensation	—	—	—	—	—	—	—	—	336	—	336
Net loss	—	—	—	—	—	—	—	—	—	(20,606)	(20,606)
Balance at December 31, 2019	8,350,743	7,519	46,176,715	66,186	—	—	18,704,118	—	4,945	(63,084)	(58,139)
Issuance of Series C-1 redeemable convertible preferred stock, net of issuance costs of $3,564	—	—	—	—	27,308,227	96,436	—	—	—	—	—
Conversion of convertible notes to Series C-2 redeemable convertible preferred stock	—	—	—	—	1,690,380	6,182	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	1,918,499	—	669	—	669
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	259	—	259
Issuance of common stock per restricted stock purchase agreement	—	—	—	—	—	—	7,373,163	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	3,163	—	3,163
Net loss	—	—	—	—	—	—	—	—	—	(47,352)	(47,352)
Balance at December 31, 2020	8,350,743	$ 7,519	46,176,715	$ 66,186	28,998,607	$ 102,618	27,995,780	$ —	$ 9,036	$ (110,436)	$ (101,400)

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.
STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2019	2020
Cash flows from operating activities		
Net loss	$ (20,606)	$ (47,352)
Adjustments to reconcile net loss to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	3,653	6,282
Change in fair value of warrant liabilities	(4)	1,289
Stock-based compensation expense	336	3,163
Loss on extinguishment of convertible notes	—	610
Non-cash lease expense	—	568
Amortization of debt discount and issuance costs	6	16
Changes in operating assets and liabilities:		
Accounts receivable	4,291	(3,968)
Inventory	—	(36,842)
Prepaid expenses and other current assets	(415)	(14,207)
Prepaid rent	—	(16,771)
Other non-current assets	—	(130)
Accounts payable	(253)	4,523
Accrued liabilities	263	8,114
Deferred rent	(374)	—
Deferred revenue	—	183,084
Operating leases	—	(337)
Other non-current liabilities	—	4,500
Interest on finance leases	107	113
Net cash, cash equivalents and restricted cash (used in) provided by operating activities	(12,996)	92,655
Cash flows from investing activities		
Purchase of property and equipment	(2,945)	(76,034)
Expenditures for software development	—	(2,114)
Net cash, cash equivalents and restricted cash used in investing activities	(2,945)	(78,148)
Cash flows from financing activities		
Proceeds from issuance of Series C-1 redeemable convertible preferred stock	—	100,000
Proceeds from convertible notes	—	5,563
Payments for issuance costs of Series C redeemable convertible preferred stock	—	(3,564)
Exercise of common stock options	12	1,079
Proceeds from debt	4,084	1,658
Repayment of debt	—	(2,571)
Payments for finance leases	(486)	(1,922)
Net cash, cash equivalents and restricted cash provided by financing activities	3,610	100,243
Net increase (decrease) cash, cash equivalents and restricted cash	(12,331)	114,750
Cash, cash equivalents and restricted cash, beginning balance	26,836	14,505
Cash, cash equivalents and restricted cash, ending balance	$ 14,505	$ 129,255
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 14,328	$ 121,578
Restricted cash, current	—	6,000
Restricted cash, non-current	177	1,677
Total cash, cash equivalents and restricted cash	$ 14,505	$ 129,255
Supplemental disclosure for cash flow information		
Cash paid for interest	$ 152	$ 340
Supplemental disclosure for non-cash investing and financing matters		
Early exercised stock options liability	$ —	$ 152
Conversion of convertible notes to Series C-2 redeemable convertible preferred stock	$ —	$ 6,182
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 11,269
Equipment obtained under capital lease obligations	$ 346	$ —
Purchase of property and equipment included in accounts payable	$ 110	$ 18,156

The accompanying notes are an integral part of these financial statements.

NOTE 1. BUSINESS AND BASIS OF ACCOUNTING

Organization and Description of Business

Cue Health Inc. (the "Company") was originally formed in the State of California on January 26, 2010, prior to being incorporated in the State of Delaware on December 14, 2017. The Company is a healthcare technology company committed to revolutionizing the healthcare experience by providing individuals with a convenient and connected diagnostic platform that bridges the physical and virtual care continuums. The Company's proprietary platform, the Cue Health Monitoring System, comprised of the Cue Reader and Cue Test Kit, enables lab-quality diagnostics-led care at home, at work or at the point of care. This platform is designed to empower stakeholders across the healthcare ecosystem, including individuals, enterprises, healthcare providers and payors, and public health agencies with paradigm-shifting access to diagnostic and health data to inform care decisions. The Company's headquarters are located in San Diego, California.

Liquidity and Capital Resources

The Company has incurred losses since inception. As of December 31, 2020, the Company has an accumulated deficit of $110.4 million and cash and cash equivalents of $121.6 million. For the year ended December 31, 2020, the Company also had a net loss of $47.4 million and net cash inflow from operations of $92.7 million. As of December 31, 2020, the Company had outstanding debt of $5.4 million, lease liabilities of $14.4 million, and a $9.0 million obligation related to a legal settlement of a contract dispute. As described in Note 18, *Subsequent Events*, in February 2021, the Company obtained a revolving line of credit with a maximum principal amount of $130.0 million. However, the Company may not meet the required debt covenants at times over the next twelve months without additional funding.

Historically, the Company has primarily funded its operations through cash from operating activities, including the U.S. DoD Advance, net proceeds from the sale of the Company's redeemable convertible preferred stock and warrants, and indebtedness. Management believes that the current available cash and cash equivalents may not be sufficient to fund the Company's planned expenditures and meet its obligations for at least twelve months following the financial statement issuance date. As a result, there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the financial statements for the year ended December 31, 2020. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern may depend upon its ability to generate revenue and raise additional funding. Management intends to generate revenue through sales of its COVID-19 test and to raise additional capital through equity offerings and expanding its borrowing capacity. While the Company has historically been successful in obtaining financing, there can be no assurance that such additional financing, if necessary, will be available or, if available, that such financings can be obtained on satisfactory terms. If the Company is unable to generate sufficient revenue or raise capital when needed or on satisfactory terms, the Company's management plans to curtail planned expenditures on certain programs, primarily the expansion of its research and development function. The planned measures are not expected to affect near-term manufacturing capacity.

Basis of Accounting

The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, the fair value of the Company's common and redeemable convertible preferred stock, the fair value of financial instruments measured at fair value, equity based compensation expense, the recoverability

of its long-lived assets and net deferred tax assets (and related valuation allowance). The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. In addition, the guidance for segment reporting indicates certain quantitative materiality thresholds. The Company views its operations and manages its business in one operating segment which is consistent with how the Chief Executive Officer, who is the chief operating decision maker, reviews the business, makes investment and resource allocation decisions, and assesses operating performance. All revenue to date is from customers located in the United States and all long-lived assets are located in the United States.

COVID-19 Impact

The novel coronavirus ("COVID-19") that was declared a global pandemic by the World Health Organization in March 2020 adversely impacted global commercial activity but served as a catalyst to accelerating the Company's product pipeline. The Company's first commercially available diagnostic test for the Cue Health Monitoring System is the Cue COVID-19 Test for ribonucleic acid of SARS-CoV-2, the virus that causes COVID-19. The Company began selling and recording product revenue for its Cue COVID-19 Test in August 2020 after obtaining an Emergency Use Authorization ("EUA") from the Federal Drug Administration ("FDA") in June 2020. Currently, 100% of the Company's revenue is derived from the Cue COVID-19 Test. Given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

In December 2020, the FDA issued EUAs for two COVID-19 vaccines. The widely administered use of an efficacious vaccine or new therapeutic treatment for COVID-19 may reduce the demand for the Cue COVID-19 Test and, as a result, the COVID-19 diagnostic testing market may not develop or grow substantially. Given the rapid development of events surrounding the pandemic, there is uncertainty to the Company's future results and performance.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Restricted Cash

Restricted cash consists primarily of cash that serves as collateral for the Company's standby letters of credit. Any cash that is legally restricted from use is classified as restricted cash. If the purpose of restricted cash relates to acquiring long-term assets, liquidating a long-term liability, or is otherwise unavailable for a period longer than one year from the balance sheet date, the restricted cash is classified as a long-term asset. Otherwise, restricted cash is presented in current assets in the balance sheets.

Accounts Receivable

The Company sells its Cue Health Monitoring System test directly to government entities, healthcare providers, commercial businesses, and through agreements with distributors, and the Company evaluates the creditworthiness of significant customers. The Company did not record an allowance for doubtful accounts for potential credit losses as of December 31, 2019 and 2020.

Concentration of Credit Risk and Other Risk and Uncertainties

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and trade accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and the deposits are held with large financial institutions.

The Company had two customers that represented more than 10% of total product revenue for the year ended December 31, 2020, at 58% and 22%, respectively. For the year ended December 31, 2019, the Company did not have any product revenue. See Note 3, *Revenue Recognition*.

As of December 31, 2020, accounts receivable from three customers with balances due in excess of 10% of total accounts receivable were 31%, 29% and 20%, respectively.

The Company purchases certain components for its products from a single supplier. A change in or loss of these suppliers could cause a delay in filling customer orders and a possible loss of sales, which could adversely affect results of operations.

Inventories

Inventory is valued at lower of cost or net realizable value on a first in, first out basis. Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead. Inventory owned by the Company that is on hand with contract manufacturers is disclosed as inventory on consignment. Provisions for excess and obsolete inventory are primarily based on the Company's estimates of forecasted sales, usage levels, and expiration dates, as applicable for certain disposable products, and assumptions about obsolescence. Unabsorbed manufacturing costs are treated as expense in the period incurred.

Fair Value Measurements and Financial Instruments

The carrying value of the Company's cash and cash equivalents, accounts receivables and accounts payable approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the Company's long-term borrowings approximates its fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's redeemable convertible preferred stock warrant liabilities are measured at fair value on a recurring basis and are classified as Level 3 liabilities. The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in current period earnings.

Property and Equipment, Net

Property and equipment, net, which consist of manufacturing equipment, laboratory equipment, computers and software, office equipment and leasehold improvements, are stated at cost less depreciation. Leasehold improvements are amortized on a straight-line basis over the shorter of their useful life or the remaining lease term, including any renewal periods that the Company is reasonably certain to exercise. Repair and maintenance costs that do not improve service potential or extend economic life are expensed as incurred.

The estimated useful lives are as follows:

	Years
Leasehold improvements	Shorter of the estimated useful life or lease term
Machinery and equipment	3-7
Furniture and fixtures	7

Amortization of assets recorded under finance leases (capital leases for 2019) is included in depreciation and amortization expense.

The Company completed a review of the estimated useful lives of its assets upon receiving FDA EUAs of the Company's Cue COVID-19 Test in June 2020. This review, based on expected technological advances and demand expectations, reduced the useful life of laboratory equipment from seven to five years and the useful life of manufacturing equipment from seven to three years. The change in useful lives was accounted for as a change in accounting estimate on a prospective basis effective June 1, 2020. For the year ended December 31, 2020, the change in estimate resulted in an increase in depreciation and amortization expense of $3.2 million, an increase in net loss of $3.2 million and an increase in basic and diluted net loss per share of $0.20.

Intangible Assets

Intangible assets are recorded at cost and amortized on a straight-line basis over their estimated useful lives. Intangible assets consist of capitalized software costs incurred in the development of the Cue Health App (the "App"). The Company determined that costs incurred during the application development stage that are directly related to the actual development of the software application are capitalized, while costs incurred in the preliminary project and post implementation stage are expensed as incurred. Additionally, indirect costs related to the software development during the application development stage are expensed as incurred. As the App is constantly updated to the next version once it has reached technological feasibility, the Company separates costs on a reasonable basis between maintenance and upgrades that extend the functionality and useful life of the App. The maintenance costs are expensed as incurred. The Company has concluded that given the rapid changes in technology, the software has a relatively short useful life of three years and is amortized on a straight-line basis. Amortization expense related to the App is recorded in cost of product revenue.

Reclassifications

Depreciation and amortization expense was previously presented under operating costs and expenses and was reclassified to research and development and general and administrative expenses for the years ended December 31, 2019 and 2020. Loss on extinguishment of debt for the year ended December 31, 2020 was also reclassified into interest expense.

Leases

The Company determines if an arrangement is a lease at inception and if so, determines whether the lease qualifies as an operating or finance lease. Lease balances are included in the balance sheets as right-of-use assets and lease liabilities.

Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Right-of-use assets and liabilities are recognized at lease commencement date based on the present value of lease payments over the lease term. When the Company's leases do not provide an implicit rate, an incremental borrowing rate is used based on the information available at commencement dates in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow over a similar term, and on a collateralized basis, an amount equal to the lease payments in a similar economic environment. The Company's lease terms may include options to extend or terminate the lease when the Company is reasonably certain that it will exercise such options. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Deferred Rent (Prior to adoption of Accounting Standards Codification ("ASC") 842)

Rent expense is recorded on a straight-line basis over the term of the lease, which includes the construction build-out period and lease extension periods, if appropriate. The difference between rent payments and straight-line rent expense is recorded as deferred rent and included in accrued liabilities on the balance sheets. Landlord allowances are amortized on a straight-line basis over the lease term as a reduction to rent expense.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or an asset group may not be recoverable. If such triggering event is determined to have occurred, the asset's or asset group's carrying value is compared to the future undiscounted cash flows expected to be generated. If the carrying value exceeds the undiscounted cash flows of the asset, then an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value. There were no impairment indicators and no impairment was recorded for the years ended December 31, 2019 and 2020.

Common Stock Warrants

Common stock warrants are measured at their estimated fair value upon issuance and recorded in additional paid-in capital. Common stock warrants are classified as equity and no subsequent remeasurement is required.

Redeemable Convertible Preferred Stock Warrants

The Company accounts for its redeemable convertible preferred stock warrants as liabilities based upon the characteristics and provisions of each instrument. The redeemable convertible preferred stock warrants classified as liabilities are recorded on the Company's balance sheets at their fair values on the date of issuance and are revalued on each subsequent balance sheet date, with fair value changes recognized as increases or reductions in the statement of operations.

Revenue Recognition

Product Revenue

The Company generates revenue from the sale of its Cue Health Monitoring System to government entities, healthcare providers, commercial customers, and through agreements with distributors. See Note 3, *Revenue Recognition*, for details.

The Company considers purchase orders, which are governed by agreements with customers, to be a contract with a customer. The contract terms with customers range in length, from one-time purchases, six-month commitments or twelve-month commitments. The timing of revenue recognition is based on the satisfaction of performance obligations promised to the customer. Cue Readers, the Cue Enterprise Dashboard and API, and Cue Test Kits, composed of Cue Cartridges and Cue Wands, are considered distinct performance obligations. The Cue Health App is integral to the functionality of the Cue Reader and these components form a single performance obligation. Revenue allocated to Cue Readers and Cue Test Kits is recognized when control of the promised goods has transferred to customers, generally upon shipment, in an amount that reflects the consideration the Company expects to receive in exchange for those goods. Revenue allocated to the Cue Enterprise Dashboard and API is recognized ratably over the term of the service. The Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Returns due to defects are estimated to be immaterial.

The transaction price is measured as the amount of consideration the Company expects to receive in exchange for the goods transferred to customers. A contract's transaction price is allocated to each distinct performance obligation on a relative standalone selling price basis. The Company estimates standalone selling prices for groups of customers with similar circumstances and characteristics.

The Company recognize receivables when there is an unconditional right to payment, which represents the amount the Company expects to collect in a transaction and is most often equal to the transaction price in the contract. Payment terms are typically 30 days.

The Company excludes from the measurement of the transaction price all taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction and collected by the entity from a customer.

During the year ended December 31, 2020, the Company generated $15.4 million in product revenue, of which $8.9 million was revenue from government entities and $6.5 million from its other customers.

Deferred Revenue

In October 2020, the Company received a $184.6 million upfront payment from the United States government (the "U.S. government") to increase production capacity of its Cue COVID-19 Test. The Company concluded that

the activities related to increasing production do not represent a performance obligation as those activities do not transfer a product or service to the customer. Instead, the upfront payment is an advanced payment for future goods or services because the agreement with the U.S. government included an option to renew the contract which included a material right to obtain products in a future contract at a specified discount, subject to a price floor, from prices offered to commercial customers with similar volume of purchases.

Deferred revenue is recognized upon satisfaction of performance obligations by reference to the total goods or services expected to be provided to the customer, including an estimate of future performance obligations under expected contract renewals, and the corresponding expected consideration.

Grant and Other Revenue

Arrangements under which it receives grants to conduct research and development activities constitute non-exchange transactions. Revenue from such is recognized to the extent of costs incurred in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory performance obligations are outstanding. Costs are included in research and development expenses. See Note 3, *Revenue Recognition*, for details regarding the Company's grant arrangement with the Biomedical Advanced Research and Development Authority ("BARDA").

The Company may enter into collaboration agreements with third parties to conduct research and development activities. The Company evaluates its collaboration agreements for proper classification in its statements of operations based on the nature of the underlying activity. When the Company has concluded that it has a customer relationship with one of its collaborators, the Company follows the guidance in ASC Topic 606, *Revenue from Contracts with Customers*. See Note 3, *Revenue Recognition*, for details regarding the Company's collaboration agreement with Janssen.

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. Contract assets at the beginning of and end of the year ended December 31, 2020, as well as changes in the balance, were not material.

Contract liabilities primarily relate to the $184.6 million upfront payment received from the U.S. government in October 2020. During the year ended December 31, 2020, the Company recognized $2.3 million in product revenue from the upfront payment resulting in a balance of $182.3 million. During the year ended December 31, 2020, the Company also received $0.8 million in non-refundable down payments from one customer that was deferred as of December 31, 2020. Contract liabilities are recorded in current and non-current deferred revenue on the balance sheets with a total balance of $183.1 million as of December 31, 2020.

Cost of Product Revenue

Cost of product revenue includes the cost of materials, direct labor, inclusive of salaries and other related costs, including stock-based compensation, depreciation, and manufacturing overhead costs used in the manufacturing of the Cue Test Kits as well as contract manufacturing costs associated with production of the Cue Readers. Cost of product revenue also includes amortization of intangible assets.

Shipping and Handling Costs

The Company elected to account for shipping and handling as activities to fulfill the promise the goods and records them cost of product revenue.

Sales and Marketing Expenses

Sales and marketing expense consist primarily of salaries and other related costs, including stock-based compensation, for personnel in sales and marketing, customer support and business development functions.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses are primarily comprised of costs and expenses for salaries and other related costs, including stock-based compensation,

associated with research and development personnel, contract services, laboratory supplies, facilities, depreciation, and outside services. Costs associated with the Company's grant and collaboration agreements as well as costs associated with products produced for research and development purposes are recorded within research and development expenses.

Accrued Research and Development Costs

The Company records accrued expenses for estimated costs of its research and development activities conducted by third-party service providers, which include clinical trial activities, based on the estimated amount of services or supplies provided but not yet invoiced and include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. Any payments made in advance of services or supplies provided are recorded as prepaid assets, which are expensed as the services or supplies are received.

The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. Significant judgments and estimates are made in determining the accrued balance in each reporting period. As actual costs become known, the Company adjusts its accrued estimates.

General and Administrative Expenses

The Company's general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation, for personnel in its executive, finance, corporate and business development and administrative functions. General and administrative expense also includes professional fees for legal, patent, accounting, information technology, depreciation, auditing, tax and consulting services, travel expenses and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses.

Fair Value of Common Stock

The fair value of the shares of common stock underlying the Company's stock-based awards was estimated on each grant date by its board of directors. In order to determine the fair value of its common stock underlying option grants, the Company's board of directors considered, among other things, valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Stock-Based Compensation

The Company estimates the fair value of stock options using the Black-Scholes-Merton ("BSM") option pricing model on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally three to four years; however, the Company's equity compensation plans provide for any vesting schedule as the Company's Board of Directors may deem appropriate. The Company recognizes forfeitures as incurred.

The BSM option pricing model incorporates various estimates, including the fair value of the Company's common stock, expected volatility, expected term and risk-free interest rates. The weighted-average expected term of options was calculated using the simplified method. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility incorporates the historical volatility over the expected term of the award of comparable companies whose share prices are publicly available. The risk-free interest rate for periods within the contractual term of the option is based on the U.S. Treasury yield in effect at the time of grant. The dividend yield was zero, as the Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive loss and, therefore, the Company's comprehensive loss was the same as its reported net loss.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would adjust the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Correction of an Immaterial Error

Certain stock-based compensation expenses were not recognized by the Company in periods prior to 2019. This prior period error was recognized as a $2.0 million adjustment to the Company's accumulated deficit and additional paid-in-capital as of January 1, 2019.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02"), which requires a lessee to recognize most leases on the balance sheet as lease liabilities with corresponding right-of-use assets. On January 1, 2020, the Company adopted Topic 842, utilizing the modified retrospective transition method. The Company will continue to report financial information for fiscal years prior to 2020 under the previous lease accounting standards and, as such, prior comparative periods have not been recast. In addition, the Company elected the package of practical expedients permitted under the transition guidance in Topic 842. As a result of this election, the Company was not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. The Company elected to account for lease and non-lease components as a single lease component. This election primarily relates to the Company's real estate leases.

Additionally, the Company elected certain practical expedients on an ongoing basis, including the practical expedient for short-term leases pursuant to which a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize a lease liability and right-of-use for leases with a term of 12 months or less and that do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. The Company has applied this accounting policy to all asset classes in its portfolio and recognizes the lease payments for such short-term leases in income from continuing operations on a straight-line basis over the lease term. The Company recorded right-of-use assets and operating lease liabilities of $8.4 million upon adoption of Topic 842 as of January 1, 2020.

See Note 8, *Leases*, for more information on the impact of the adoption of ASU 2016-02 and related disclosures.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* (Topic 230) Restricted Cash, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and restricted cash. Therefore, amounts described as restricted cash should be included with cash and cash equivalents when reconciling the beginning of period and end of period amounts shown on the statement of cash flows. The standard is effective for all entities for fiscal years beginning after December 15, 2018. The Company adopted this guidance on January 1, 2019.

In August 2018, the FASB ASU No. 2018-13, *Fair Value Measurement* (Topic 820), which eliminates, adds and modifies certain disclosure requirements for fair value measurements. The modified standard eliminates the requirement to disclose changes in unrealized gains and losses included in earnings for recurring Level 3 fair value measurements and requires that changes in unrealized gains and losses be included in other comprehensive income for recurring Level 3 fair value measurements of instruments. The standard also requires the disclosure of the range and weighted average used to develop significant unobservable inputs and how weighted average is calculate for recurring and nonrecurring Level 3 fair value measurements. The amendment is effective for fiscal years beginning after December 15, 2019 and interim periods within that fiscal year with early adoption permitted. The Company adopted ASU 2018-13 on January 1, 2019. The adoption of this standard did not have a material impact on the Company's financial statements. For the new disclosures regarding the Company's level 3 fair value measurements, see Note 12, *Fair Value Measurements*.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326) – Measurement of Credit Losses on Financial Instruments. The standard provides guidance for estimating credit losses on certain types of financial instruments, including trade receivables, by introducing an approach based on expected losses. The expected loss approach will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. ASU 2017-13 also amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. The FASB has issued several amendments to the standard. In November 2019, the FASB amended the standard with the issuance of ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates. The amendment revised the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of ASU 2016-13 on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which simplifies the accounting for income taxes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020 for public companies and for fiscal years beginning after December 15, 2021 for all other entities and early adoption is permitted. The Company has not yet evaluated the impact the adoption of ASU 2019-12 will have on the Company's financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt — Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging — Contracts in Entity's Own Equity* (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). The ASU simplifies the accounting for convertible instruments by removing certain models in Subtopic 470-20 and revises the guidance in Subtopic 815-40 to simplify the accounting for contracts in an entity's own equity. ASU 2020-06 is effective for reporting periods beginning after December 15, 2023 with early adoption permitted for reporting periods beginning after December 15, 2020. The amendment is to be adopted through either a modified retrospective or fully retrospective method of transition. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements and its adoption method.

NOTE 3. REVENUE RECOGNITION

Department of Defense Contract (Product Revenue)

In October 2020, the Company entered into a $480.9 million agreement (as amended in March 2021, the "U.S. DoD Agreement") with the U.S. government for the purchase of its Cue COVID-19 Test to meet the unprecedented demand for rapid and accurate molecular diagnostic testing. The U.S. DoD Agreement provides $184.6 million to facilitate the scaling of the Company's manufacturing capacity, which was received upon signing the contract ("U.S. DoD Advance"). The U.S. DoD Agreement does not provide for the funds to be utilized in any specific manner beyond furthering the purposes of the agreement. We are not required to segregate, nor are we required to obtain the approval of the U.S. government to use, funds advanced to us under the agreement. The remaining $296.3 million of the agreement is for the sale of Cue Readers, Cue COVID-19 Test Kits and Cue Control Swab Packs. The U.S. DoD Agreement also provides that, as soon as possible after the commencement of the initial U.S. DoD Agreement, we and the U.S. government are expected to negotiate in good faith to enter into a follow-on supply agreement based on federal acquisition regulations (a FAR-based contract). The existing agreement provides the U.S. DoD with the right to purchase no more than 45% of our quarterly production for the duration of the follow-on contract at a

specified discount, subject to a price floor as part of this follow-on contract. The U.S. government is also entitled to certain administrative reporting but does not receive the right to any intellectual property or know-how.

To satisfy the terms of the arrangement, the Company must provide the U.S. government the contractual units and demonstrate its ability to manufacture an average of approximately 100,000 Cue Cartridges per day over a consecutive 7-day period by October 2021. Subject to limited exceptions, the U.S. government is entitled to be the exclusive purchaser of our entire production through the completion of the project. Pursuant to the U.S. DoD Agreement, we are permitted to honor certain contractual obligations that existed prior to the effective date of the U.S. DoD Agreement and may use a reasonable number of tests for internal workforce testing as well as for marketing, demonstration and evaluation of our products and business development. Furthermore, we are able to seek waivers from the U.S. government to sell certain of our products to additional customers. The agreement term ends upon final payment under the agreement and is anticipated to be completed in October 2021. The U.S. government may terminate the agreement for convenience, but the Company is entitled to all payments received, including the U.S. DoD Advance as well as a good faith negotiation for work performed through the termination date, subject to the U.S. government retaining the right to place priority orders for up to a year following termination for other diagnostic tests manufactured using the manufacturing equipment purchased with U.S. government funds under the agreement. The U.S. government also has certain termination for cause remedies if the Company were to exit or abandon its COVID-19 business.

The U.S. DoD Agreement is within the scope of ASC Topic 606, *Revenue from Contracts with Customers*. The delivery of the Cue COVID-19 Test products are separate performance obligations since they are capable of being distinct and are distinct within the U.S. DoD Agreement. The promise of a future specified discount, subject to a pricing floor, represents a separate performance obligation as it qualifies as a material right. Activities related to production scaling pursuant to the U.S. DoD Advance, the right to up to 45% capacity in a future contract, and administrative reporting do not represent the transfer of good or services to the U.S. government, so they are not separate performance obligations.

The transaction price is fixed and does not include variable consideration.

At contract inception, consistent with a similar class of customer, the Company determined stand-alone selling price and noted all products were sold at a discount, so the transaction price was allocated on a relative standalone selling price basis to all products. The Company elected to account for the material right per the practical alternative approach in which the transaction price is allocated to the optional goods and the corresponding consideration it expects to receive (hypothetical contract) since the same Cue COVID-19 Test products sold in the U.S. DoD Agremeent would be included in any follow-on contract. The U.S. DoD Advance was recorded in deferred revenue and will be recognized upon satisfaction of performance obligations. Significant judgment is applied in determining how deferred revenue will be recognized, including estimating future quantities, delivery schedules, pricing and contract duration from the U.S. government, which can have a significant impact to revenue recognition.

A performance obligation is satisfied once the control of a product is transferred to the customer or the service is provided to the customer, meaning the customer has the ability to use and obtain the benefit of the goods or service. The U.S. government does not control the product prior to shipment because it does not have the ability to use and obtain the benefit of the products and the contractual restrictions do not limit the alternative future use of the products. Based on an analysis of the various indicators of control, revenue is recognized point-in-time upon shipment.

Deferred revenue related to the U.S. DoD Advance as of December 31, 2020, was $182.3 million. Of this amount, $114.9 million is classified as current as of December 31, 2020, based on amounts expected to be realized within the next year.

BARDA Contract

During 2018, the Company entered into a cost reimbursement contract with BARDA that was effective through January 2021 for a total contract amount of $14.0 million (the “BARDA Contract”). The objective of the BARDA Contract is to accelerate the development, validation, regulatory authorization and commercialization of the Company’s products. The BARDA Contract requires the Company provide reporting deliverables that include monthly technical and annual reports and a final report, but BARDA is not entitled to any know-how or intellectual property.

In March 2020, BARDA exercised an option in the BARDA Contract for a second phase to accelerate development, validation and FDA clearance of the Company's Cue COVID-19 Test for an additional contract value of $13.7 million. The period of performance related to the second phase extends to January 2023.

In May 2020, the original BARDA Contract was amended to increase the total value from $14.0 million to $21.8 million and to extend the contract term to January 2022.

The Company recognizes revenue from its BARDA Contract in the period during which the related costs are incurred, provided that the conditions under which the grants and contracts were provided have been met and only perfunctory performance obligations are outstanding. Costs are included in research and development expenses.

Janssen Contract

In August 2019, the Company entered into a collaboration agreement with Janssen Pharmaceuticals, Inc. ("Janssen") to research the feasibility of the Company's diagnostic product with a total contract value of $0.6 million ("Janssen Contract"). Janssen is entitled to the underlying research data. The Company owns all resulting intellectual rights. Revenue from the Janssen Contract was recorded over time on an input method as costs were incurred. Outstanding accounts receivable from Janssen was $0.2 million at December 31, 2019. There was no activity related to this agreement during the year ended December 31, 2020. Costs are included in research and development expenses.

NOTE 4. INVENTORIES

As of December 31, 2019, and 2020, the Company's inventories consisted of the following:

	December 31,	
	2019	2020
Raw materials	$ —	$ 29,948
Work-in-process	—	4,957
Finished goods	—	1,645
Inventory on consignment	—	1,081
Reserve	—	(789)
Total inventories	$ —	$ 36,842

Inventory on consignment represents inventory owned by the Company that is on hand with contract manufacturers. During the year ended December 31, 2020, the Company recorded charges of $0.8 million related to excess and obsolete inventory in cost of sales as a result of an ongoing assessment of inventory on hand for each product and the continuous improvement and innovation of its products. During the year ended December 31, 2020, $2.1 million of capitalized depreciation and amortization costs were expensed to cost of product revenue as inventory was sold. As of December 31, 2020, inventory included $0.6 million of capitalized depreciation and amortization costs.

NOTE 5. PREPAID EXPENSES

As of December 31, 2019, and 2020, the Company's prepaid expenses consisted of the following:

	December 31,	
	2019	2020
Prepaid expense	$ 669	$ 5,152
Prepaid inventory	—	8,695
Total prepaid expenses	$ 669	$ 13,847

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of December 31, 2019, and 2020, the Company's property and equipment, net consisted of the following:

	December 31,	
	2019	2020
Construction in progress	$ 614	$ 83,353
Machinery and equipment	13,683	26,972
Leasehold improvements	4,847	2,897
Furniture and fixtures	388	683
Property and equipment	19,532	113,905
Accumulated depreciation	(7,902)	(10,222)
Total property and equipment, net	$ 11,630	$ 103,683

Depreciation expense related to property and equipment was $3.7 million and $6.2 million for the years ended December 31, 2019 and 2020, respectively. During the year ended December 31, 2020, $2.7 million of depreciation and amortization expense was capitalized into inventory during the manufacturing process. The carrying value of assets under finance leases (capital leases for 2019) within machinery and equipment as of December 31, 2019 and 2020 was $1.4 million and $4.8 million, respectively.

During 2020, the Company revised the useful life of certain property and equipment. Refer to the Property and Equipment section of Note 2 for further information regarding the useful life change in accounting estimate and the Company's current useful lives of its property and equipment.

NOTE 7. INTANGIBLE ASSETS

As of December 31, 2019, and 2020, the Company's intangible assets consisted of the following:

	December 31,	
	2019	2020
Developed software	$ —	$ 2,114
Accumulated amortization	—	(76)
Total intangible	$ —	$ 2,038

Amortization expense related to intangible assets for the year ended December 31, 2020 was $0.1 million. Estimated amortization expense for each of the years ending December 31 is as follows:

2021	$ 705
2022	705
2023	628
Total amortization expense	$ 2,038

NOTE 8. LEASES

The Company leases real estate and manufacturing and laboratory equipment which are used in the Company's manufacturing, research and development, and administrative activities. The Company identifies a contract that contains a lease as one which conveys a right, either explicitly or implicitly, to control the use of an identified asset in exchange for consideration. These arrangements are classified as finance leases and operating leases. Finance leases consist of laboratory and manufacturing equipment with remaining terms ranging from 1 year to 3 years. The Company's operating leases relate to the Company's manufacturing facilities and office space and have remaining terms from 7 year to 9 years. Certain leases have renewal options that allow us to extend the term of the lease term. An option to renew or terminate the current lease term of a lease arrangement is included in the lease term if the Company is reasonably certain to exercise that option.

The Company does not recognize right-of-use assets and lease liabilities for short-term leases, which have terms of 12 months or less, on its balance sheet. For the long-term lease arrangements that are recognized on the Company's balance sheet, right-of-use assets and lease liabilities are initially measured and recognized at the lease

commencement date based on the present value of lease payments due over the lease term. As the implicit interest rates of the Company's lease arrangements are generally not readily determinable, the Company applies its incremental borrowing rate to calculate the lease liability at the lease commencement date. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In June 2020, the Company entered into a lease agreement for a building to be used as a manufacturing facility. As the construction of improvements to bring the facility to its intended use was ongoing as of December 31, 2020, the lease had not commenced as of that date. The lease has a term of ten years and future minimum rent payments are approximately $24.9 million.

In addition to rent, the lease requires the Company to pay additional amounts for taxes, insurance, maintenance and other operating expenses. The base rent includes an allowance of $125 per square foot to cover some portion of the construction of the tenant improvements that began in July 2020.

In October 2020, the Company leased a second building, also to be used as a manufacturing facility. The lease has an initial term of five years and the company is reasonably certain to exercise a renewal option to extend the lease term for an additional five years. The future minimum rent commitment is $24.0 million. In addition to rent, the lease requires the Company to pay additional amounts for taxes, insurance, maintenance and other operating expenses. The Company will also receive a tenant reimbursement allowance of $1.6 million to cover some portion of the construction of the tenant improvements that began in October 2020. As the construction of improvements to bring the facility to its intended use was ongoing as of December 31, 2020, the lease had not commenced as of that date.

The Company made payments of $16.8 million for landlord-owned improvements related to the two leases above. The payments have been capitalized in prepaid rent and will be reflected in right-of-use assets upon commencement of the leases.

The right-of-use assets and lease liabilities recognized on the Company's balance sheet as of December 31, 2020 were as follows:

		December 31, 2020	
	Balance Sheet Location	**Operating Leases**	**Finance Leases**
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 8,281	
Right-of-use assets finance leases	*Property and equipment, net*		$ 4,837
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	797	
Finance lease liabilities (current)	*Finance lease liabilities, current*		1,249
Operating lease liabilities (non-current)	*Operating leases liabilities, net of current portion*	10,472	
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*		1,857

The components of lease expense for the year ended December 31, 2020 were as follows:

	Year Ended December 31, 2020
Operating lease cost	$ 1,552
Finance lease cost:	
Amortization of right-of-use assets	570
Interest on lease liabilities	113
Total lease cost	$ 2,235

As of December 31, 2020, the maturities of the Company's operating and finance lease liabilities were as shown below:

	Operating Leases	Finance Leases
2021	$ 1,736	$ 1,399
2022	1,785	1,169
2023	1,836	781
2024	1,889	—
2025	1,941	—
Thereafter	6,944	—
Total lease payments	16,131	3,349
Less: Imputed interest	(4,862)	(243)
Total	$ 11,269	$ 3,106

The supplemental cash flow information related to leases for the twelve months ended December 31, 2020 were as follows:

	Year Ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 1,287
Operating cash flows from finance leases	$ 113
Financing cash flows from finance leases	$ 1,922
Right-of-use assets obtained in exchange for lease liabilities:	
Operating leases	$ 8,443
Finance leases	$ 2,826

The following table presents the weighted-average remaining lease term and discount rate information related to the Company's operating and finance leases as of December 31, 2020:

	December 31, 2020	
	Operating Leases	Finance Leases
Weighted-average remaining lease term	8.4 years	2.5 years
Weighted-average discount rate	8.7%	6.5%

Disclosures related to periods prior to adoption of Topic 842

The Company's future minimum rental commitments on non-cancelable leases as of December 31, 2019, under Topic 840, were as follows:

	Operating Leases	Capital Leases
2020	$ 1,127	$ 509
2021	1,675	372
2022	1,725	142
2023	1,777	9
2024	1,830	—
Thereafter	8,551	—
Total future minimum lease payments	$ 16,685	$ 1,032

Rent expense for the year ended December 31, 2019 was $0.9 million.

Carroll Canyon Lease

In December 2018, the Company entered into a lease agreement for office and laboratory space in San Diego. The Lease has a term ten years and seven months and there are no renewal options. The future minimum rent commitment is $10.8 million. In addition to rent, the Lease requires the Company to pay additional amounts for taxes, insurance, maintenance and other operating expenses. The Company also received tenant reimbursement allowance of $4.4 million to cover hard costs such as flooring, electrical, plumbing and HVAC, as well as other tenant improvements.

The Company is not the legal owner of the leased space. However, in accordance with ASC Topic 840, *Leases*, because of the Company's expected level of direct financial and operational involvement in the substantial tenant improvements being constructed, the Company was deemed to be the owner of the leased space for accounting purposes once it obtained control of the space at the start of construction in April 2019. As a result, the Company recorded the estimated value of the building on its balance sheets, along with construction costs incurred with a corresponding capital lease obligation for the duration of the construction period. Land lease rents and interest were immaterial. No rental payments were made prior to substantial completion of construction in October 2019. Upon substantial completion, the Company concluded it qualified for sale-leaseback accounting since the Company did not have continuing involvement in the form of purchase options, collateral guarantees, nonrecourse financing, among other matters, so the assets and liabilities were derecognized. During the year ended December 31, 2019, the Company recorded $0.9 million in tenant improvements funded by the landlord with a corresponding deferred rent liability.

In December 2019, the Company entered into a lease for a different facility with the same landlord and negotiated an option to terminate its existing office lease upon three months from the commencement of the new lease. No gain was recorded upon termination in January 2020 and the deferred rent upon termination continued to be deferred over the team of the lease.

NOTE 9. DEBT

In May 2015, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Comerica Bank ("Comerica"). The Loan Agreement provided for growth capital advances up to $2.5 million. The interest rate per the Loan Agreement was prime plus 1%. Issuance costs and third-party legal costs incurred were immaterial and were recorded as discounts to the carrying value of the loan.

The Company issued Comerica two series of warrants comprised of one warrant to purchase 20,441 shares of Series A redeemable convertible preferred stock at an exercise price of $0.91728 per share with an issuance date of May 28, 2015, and the second warrant to purchase 20,441 shares of Series A redeemable convertible preferred stock at an exercise price of $0.91728 per share with an issuance date of June 5, 2015. These warrants were immediately exercisable and will expire if unexercised ten years after issuance. The total value of these warrants upon issuance was $18,406. The fair value of the warrants upon issuance was determined using BSM option pricing model and was recorded as a discount to debt and an offsetting amount recognized as a liability. The resulting debt discount is being amortized to interest expense using the effective interest method over the term of the loan.

In September 2016, the Company entered into the First Amendment to the Loan Agreement so that the growth capital advances outstanding as of August 31, 2017 would be payable in twenty-four equal monthly installments of principal, plus all accrued interest, beginning on September 1, 2017 until the August 1, 2019 maturity date. In connection with the First Amendment, the Company issued Comerica warrants to purchase 7,631 shares of Series A redeemable convertible preferred stock at an exercise price of $0.91728 per share. These warrants were immediately exercisable and will expire if unexercised ten years after issuance. The value of these warrants upon issuance was $4,727. The fair value of the warrants upon issuance was determined using BSM option pricing model and was recorded as a discount to debt and an offsetting amount recognized as a liability. The resulting debt discount is being amortized to interest expense using the effective interest method over the term of the loan. Third-party legal costs incurred were de minimis and were expensed.

On November 27, 2018, the Company entered into the Second Amendment to replace the growth capital advances with a revolving line which provided a credit extension of up to $4.0 million maturing on June 30, 2020 and the Growth Capital A Line which provided a credit extension of up to $6.0 million with a maturity date of September 30, 2022 if the Company provides evidence satisfactory to Comerica that the option period under (and as detailed in) the BARDA Contract has been exercised. The BARDA Contract extension was exercised in March 2020 (see Note 3, *Revenue Recognition*). In connection with the Second Amendment, the Company issued warrants to

purchase 31,369 shares of Series B redeemable convertible preferred stock at an exercise price of $1.4345. These warrants were immediately exercisable and will expire if unexercised ten years after their issuance. The value of these warrants upon issuance was $22,513. The fair value of the warrants upon issuance was determined using BSM option pricing model and was recorded as a discount to debt and an offsetting amount recognized as a liability. The resulting debt discount is being amortized to interest expense using the effective interest method over the term of the loan. The interest rate per the Second Amendment was amended from prime plus 1% to prime plus 0.25%. Third-party legal costs incurred were de minimis and were expensed.

Financial covenants associated with the Second Amendment include certain borrowing base restrictions as defined in the agreement, a requirement to maintain a minimum cash balance of not less than $2.0 million, and certain reporting requirements that include an unqualified (with no going concern uncertainty) audit opinion 180 days after year-end. The Company was out of compliance with certain affirmative covenants such as issuance of financial statements within 180 days for the 2019 financial statements.

On September 25, 2019, the Company entered into the Third Amendment and Waiver to the Loan Agreement which waived previous breaches of debt covenants and extended the maturity date of the revolving line to June 30, 2021. On May 9, 2020, the Company entered into an amendment to waive the requirement to provide audited financial statements with no going concern qualification for 2019, as well as other reporting covenants through June 30, 2020. An additional waiver was obtained on July 17, 2020 to waive the 180-day reporting requirement through August 31, 2020. Subsequent to August 31, 2020, the Company obtained permission from Comerica to provide unaudited financial statements. As noted in Note 1. *Business and Basis of Accounting*, management concluded there is substantial doubt about the Company's ability to continue as a going concern for the twelve months following the issuance date of the financial statements for the year ended December 31, 2020. The Company was not in compliance with certain affirmative covenants related to this Loan Agreement as a result of a going concern uncertainty paragraph in the audit opinion so the outstanding balance of $5.4 million is included in current liabilities as of December 31, 2020.

As of December 31, 2019, and 2020, the Company had an outstanding debt balance of $6.3 million and $5.4 million and the interest rate was 5.00% and 3.50%, respectively.

NOTE 10. WARRANTS TO PURCHASE COMMON STOCK OR REDEEMABLE CONVERTIBLE PREFERRED STOCK

Common Stock Warrants

As of December 31, 2020, the Company had an outstanding warrant to purchase 75,744 shares of common stock at a purchase price of $0.40 per share. The warrant was issued on August 22, 2017 and expires on August 22, 2027. The warrant will automatically convert upon a change in control of the Company or a liquidation event. All shares subject to the warrant have vested as of December 31, 2020.

Redeemable Convertible Preferred Stock Warrants

Outstanding warrants to purchase redeemable convertible preferred shares as of December 31, 2020 were as follows:

	Shares	Exercise Price	Issuance Date	Expiration Date
Series A redeemable convertible preferred stock warrants	20,441	$0.91728	May 28, 2015	May 28, 2025
Series A redeemable convertible preferred stock warrants	20,441	0.91728	May 28, 2015	May 28, 2025
Series A redeemable convertible preferred stock warrants	7,631	0.91728	September 6, 2018	September 6, 2028
Series B redeemable convertible preferred stock warrants	31,369	1.4345	November 27, 2018	November 27, 2028

The redeemable convertible preferred stock warrants are classified as liabilities, with changes in fair value recorded through earnings, as the underlying redeemable convertible preferred shares can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company. The Company

estimated the fair value of the redeemable convertible preferred stock warrants using an option pricing model. The significant inputs to this valuation methodology included the rights, preferences and privileges of each class of Company's shares (see Note 12, *Fair Value Measurements*), and the Company's estimated equity value and volatility assumptions on the valuation date, which are based on management's analysis of comparable publicly traded peer companies.

NOTE 11. STOCKHOLDERS' EQUITY

Equity Offerings

In May 2020, the Company entered into a Convertible Note Purchase Agreement for a maximum of $12.0 million in convertible notes accruing interest at 3% per annum and maturing October 2021. The Company received proceeds of $5.6 million through the issuance date of these financial statements. The convertible notes are exercisable at a 10% (within 30 days) or 15% discount (after 45 days) upon a financing transaction in excess of $30.0 million.

In June 2020, the Company raised $105.6 million in net cash proceeds through issuance of shares of its Series C redeemable convertible preferred stock. The issuance included 27,308,227 shares of Series C-1 redeemable convertible preferred stock, par value $0.00001 per share, at $3.6619. The convertible notes entered in May 2020 were converted into 1,690,380 shares Series C-2 redeemable convertible preferred stock, par value $0.00001 per share, at $3.2957 per share at a 10% discount upon closing of the Series C redeemable convertible preferred stock issuance generating a loss on extinguishment of $0.6 million recorded in interest expense in the statements of operations.

Shares of Series A redeemable convertible preferred stock, Series B redeemable convertible preferred stock, and Series C redeemable convertible preferred stock are collectively referred to as "Preferred Shares". Significant rights, preferences and privileges of the Company's Preferred Shares are as follows:

Dividends

Preferred Shares accrue dividends accruing at a rate per annum of 8% per share based on the Preferred Shares original issue price, calculated daily, whether or not declared, however, such accrued dividends shall be non-cumulative and payable only if and when declared by the Board of Directors on Preferred Shares on a pari passu basis. If not declared by December 31 of each year any accrued dividends will be extinguished and begin to accrue anew beginning on January 1 of the following year. Additionally, the holders of Preferred Shares shall participate, on a pro rata basis, in any dividends paid on common stock or on a non-cash distribution on an as-converted basis. As of December 31, 2019, and 2020, the Board of Directors has not declared any dividends.

Liquidation

Preferred shares shall be entitled to receive, on a pari passu basis with each other and prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders on any common stock by reason of their ownership thereof, an amount equal to the greater of (i) a per share amount equal to the Series A redeemable convertible preferred stock original issue price per share of $0.91728, Series B redeemable convertible preferred stock original issue price per share of $1.4345, Series C-1 redeemable convertible preferred stock original issue price per share of $3.6619, and Series C-2 redeemable convertible preferred stock original issue price per share of $3.2957, as applicable, plus any declared but unpaid dividends, or (ii) the per share amount that would have been payable had all Preferred Shares been converted into common stock at the then effective conversion price, as applicable, immediately prior to such liquidation event.

Liquidation Event

A Liquidation Event shall include, unless the holders of at least two-thirds of the outstanding shares of Series A, B and C redeemable convertible preferred stock, voting together as a single class on as converted to Common Stock basis (the "Required Preferred Holders"), elect otherwise by written notice to the Company:

a) a merger or consolidation in which (i) the Company is a constituent party or (ii) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except in either case, in respect of any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately

prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets or intellectual property of the Company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company; or

c) the closing of the transfer (whether by merger, amalgamation, consolidation or otherwise), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than an underwriter of the Company's securities), of the Company's securities if, after such closing, such person or group of affiliated persons would hold a majority, by voting power, of the share capital or capital stock of the Company.

Conversion

The Preferred Shares are convertible into common stock at the option of the holder at any time by dividing their original issue price by the conversion price in effect at the time of conversion. The conversion price of Preferred Shares is subject to adjustments for recapitalization (i.e. stock dividends, stock splits, reorganization, reclassification, combination of shares), or upon the issuance of shares at a price less than the then current conversion price.

Preferred Shares are automatically convertible into common stock at its then effective conversion price (discussed above) (i) upon the completion of a firm underwritten public offering of the Company's common stock with net proceeds (after underwriter's discounts and commissions) of at least $50.0 million and at a price per share not less the three times the Series C-1 original issue price, or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of the Required Preferred Holders, all outstanding Preferred Shares shall automatically be converted into shares of Common Stock at the then effective applicable Conversion Price.

Voting Rights

The holders of the Preferred Shares are entitled to vote together with the Common Stock as a single class on an as-converted basis upon any matter submitted to the stockholders for a vote, with each holder of outstanding shares of the series of Preferred Shares entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of the applicable series of Preferred Shares held by holder are convertible.

So long as 6,988,161 Preferred Shares remain outstanding, holders of Preferred Shares are entitled, voting together as a separate class, to elect three directors.

So long as at least 1,449,915 shares of Series C redeemable convertible preferred stock remain outstanding, the holders of the Series C redeemable convertible preferred stock are entitled, voting together as a separate class, to elect one director.

The holders of Common Stock, voting together as a separate class, are entitled to elect one director, however, at such time that the Corporation's Chief Executive Officer ceases to serve as the Chief Executive Officer, the holders of the Common Stock are entitled to elect two directors, one of whom shall be the Chief Executive Officer of the Corporation.

Redemption

Per the terms of the Company's Amended and Restated Certificate of Incorporation, in the event of a Deemed Liquidation Event the Company will redeem the redeemable convertible preferred shares at a price per share equal to the applicable Liquidation Amount. If the available proceeds are not sufficient to redeem all outstanding Preferred Shares, the Company shall redeem a pro rata portion of Preferred Shares to the fullest extent of the available proceeds. Remaining available proceeds, if any, will then be distributed to the holders of common stock.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following as of December 31, 2020:

Redeemable convertible preferred stock	83,526,065
Warrants to purchase redeemable convertible preferred stock	79,882
Common stock option grants issued and outstanding	8,344,752
Common stock reserved for future option grants	2,950,871
Common stock warrants	75,744
Total common shares reserved for future issuance	94,977,314

NOTE 12. FAIR VALUE MEASUREMENTS

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy:

December 31, 2019	Recurring Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Redeemable convertible preferred stock warrant liabilities	$ —	$ —	$ 42	$ 42

December 31, 2020	Recurring Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Redeemable convertible preferred stock warrant liabilities	$ —	$ —	$ 1,331	$ 1,331

The following table includes a rollforward of redeemable convertible preferred stock warrant liabilities measured on a recurring basis and classified within Level 3 fair value hierarchy:

	Amount
Balance, January 1, 2019	$ 46
Issuance	—
Remeasurement	(4)
Balance, December 31, 2019	42
Issuance	—
Remeasurement	1,289
Balance, December 31, 2020	$ 1,331

The estimated fair value of redeemable convertible preferred stock warrants was determined using BSM option pricing model with the following assumptions at December 31, 2019 and 2020:

Series A redeemable convertible preferred stock warrants

	December 31,	
	2019	2020
Expected volatility	41.8%	59.9%
Expected term (years)	5.92	4.92
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.72%	0.41%
Fair value per share	$ 0.55	$ 16.83

Series B redeemable convertible preferred stock warrants

	December 31,	
	2019	2020
Expected volatility	37.2%	46.2%
Expected term (years)	8.91	7.91
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.88%	0.65%
Fair value per share	$ 0.68	$ 16.41

NOTE 13. STOCK-BASED COMPENSATION

Stock Incentive Plans

In August 2014, the Company adopted the 2014 Equity Incentive Plan ("2014 Plan") under which employees, non-employee directors and consultants of the Company may be granted either incentive stock options or non-qualified stock options to purchase shares of the Company's common stock. A total of 11,520,590 and 20,399,691 shares of common stock were reserved for issuance under the 2014 Plan December 31, 2019 and 2020 respectively. In addition, "returning shares" that may become available from time to time are added back to the plan. "Returning shares" are shares that are subject to outstanding awards granted under the 2014 Plan that expire or terminate prior to exercise or settlement, are forfeited because of the failure to vest, are repurchased, or are withheld to satisfy tax withholding or purchase price obligations in connection with such awards. The Plan allows for the early exercise of all stock options granted if authorized by the board of directors at the time of grant. As of December 31, 2020, 2,950,871 shares remain available for future grant under the 2014 Plan.

Stock Options

Options granted under the 2014 Plan have terms of ten years from the date of grant unless earlier terminated and generally vest over a three or four-year period.

The exercise price of all options granted during the year ended December 31, 2019 and 2020 was equal to the market value of the Company's common stock on the date of grant.

In December 2020, the vesting of 3,637,477 shares of common stock was accelerated and resulted in additional compensation expense of $1.7 million for the year ended December 31, 2020.

A summary of stock option activity and related information for the years ended December 31, 2019 and 2020 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2019	8,227,345	$0.38	
Granted	375,000	0.48	
Exercised	(24,250)	0.48	
Forfeited	(215,750)	0.48	
Expired	(117,594)	0.37	
Outstanding at December 31, 2019	8,244,751	0.39	6.84
Granted	2,233,042	1.41	
Exercised	(1,918,499)	0.56	
Forfeited	(78,043)	0.96	
Expired	(136,499)	0.39	
Outstanding at December 31, 2020	8,344,752	$0.61	6.44
Exercisable at December 31, 2020	6,350,005	$0.43	5.55
Vested and expected to vest at December 31, 2020	8,176,627	$0.60	6.36

The aggregate intrinsic value of options exercised was $0.8 million and $96.0 million, for the years ended December 31, 2019 and 2020 respectively. As of December 31, 2019, and 2020, the total intrinsic value of options outstanding was $0.9 million and $129.5 million, respectively.

Compensation Expense

The estimated fair value of each stock option award granted to employees was determined on the date of grant using the BSM option pricing model with the following assumptions for stock option grants for the years ended December 31, 2019 and 2020:

	2019	2020
Expected volatility	28.4%	39.6%
Expected term (years)	6.08	7.04
Expected dividend yield	0%	0%
Risk-free interest rate	1.8%	0.4%
Grant date fair value	$ 0.15	$ 0.57

The Company recognized $0.2 million and $0.7 million of stock-based compensation for stock options granted to employees and nonemployees during the years ended December 31, 2019 and 2020, respectively, that was included in general and administrative expenses.

As of December 31, 2020, there was $0.8 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 3.23 years, on a straight-line basis.

Restricted Stock Purchase Agreements with Executives

In September 2018, the Company issued a total of 2,924,130 shares of common stock pursuant to Restricted Stock Purchase Agreements with its Chief Executive Officer and Chief Product Officer in exchange for Nonrecourse Notes totaling $1.4 million to finance 100% of the cost of the shares. Due to the Nonrecourse Notes being collateralized by the stock purchased and other stock held by the purchaser, these transactions are accounted for as substantive grants of common stock options since the employee does not assume the risk of ownership. These shares are legally issued and outstanding and included on the balance sheet, but they are not treated as outstanding common stock for accounting purposes as they are deemed to be common stock options. Principal and interest payments received are recorded as a deposit liability until the Nonrecourse Notes are repaid at which time the deposit liability is transferred to additional paid-in capital.

The Nonrecourse Notes bear interest, payable annually on July 1 of each year, computed at a rate equal to 3.06% per annum. Accrued interest is also nonrecourse and is payable in arrears on each anniversary of the closing date and does not compound. The Nonrecourse Notes may be prepaid in full or in part at any time without premium or penalty and are due in September 2028. The shares are subject to repurchase by the Company at the lower of the original purchase price of $0.48 per share or fair market value upon termination from service. Vesting commenced on January 1, 2018 and the shares vest ratably monthly over four years. Compensation expense is recognized over the requisite service period.

In July 2020, the Company issued a total of 7,373,163 shares of common stock pursuant to Restricted Stock Purchase Agreements with its Chief Executive Officer and Chief Product Officer in exchange for Promissory Notes totaling $10.4 million to finance 100% of the cost of the shares, representing a per-share purchase price of $1.41. The Promissory Notes provided for the loan to the executives by the Company with the principal amounts equal to the purchase price of the common stock and bear an interest of 1.17% payable at any time without a premium or penalty. In connection with the Promissory Notes, the executive entered into Pledge Agreements whereby the shares purchased were pledged as collateral for the Promissory Notes. The Promissory Notes provide that 50% of the balance is recourse and 50% is nonrecourse.

Upon the executives' termination of service, the Pledge Agreements provide the Company the right to repurchase unvested shares are at the lower of the original purchase price of $1.41 per share or fair market value. The repurchase right lapses 1/48th per month over the four-year period, which represents and in-substance vesting of the shares from the vesting commencement date.

As the Pledge Agreements relate to the entire number of share purchased and no specific percentage of the underlying shares is aligned to the respective recourse and nonrecourse portions of the Promissory Notes and the

recourse provisions are not substantive as the Company generally does not intend to pursue collection on the recourse portion of the Promissory Notes, the Promissory Notes are considered nonrecourse in their entirety and the transaction is accounted for as stock option awards. Compensation expense will be recognized on a straight-line basis over the vesting term.

In December 2020, the Company cancelled and forgave $0.2 million of the outstanding Nonrecourse Notes related to 480,000 shares purchased by its Chief Product Officer. The forgiveness was deemed to be a modification, given the shares were significantly in-the-money, the Company determined that the principal and interest forgiven is materially consistent with the change in fair value. The unrecognized grant date fair value and the incremental fair value from the modification resulting from the forgiveness of the Nonrecourse Notes related to vested shares was recognized in stock-based compensation expense during the year ended December 31, 2020. The forgiveness of the Nonrecourse Notes were deemed to be exercises of stock options. The unvested portion of the shares will be recognized as stock-based compensation expense over the remaining vesting period. This modification resulted in $0.2 million in additional compensation expense for the year ended December 31, 2020.

Concurrently, the Company accelerated vesting of 360,516 shares of common stock subject to the 2018 restricted stock purchase agreements and 3,276,961 shares of common stock subject to the 2020 restricted stock purchase agreements that resulted in additional compensation expense of $1.7 million for the year ended December 31, 2020.

Additionally, the Company normal vesting of 741,033 shares of common stock subject to the 2018 restricted stock purchase agreements and 921,645 shares of common stock subject to the 2020 restricted stock purchase agreements that resulted in additional compensation expense of $0.8 million for the year ended December 31, 2020.

The Company estimated the fair value of these restricted shares issued for Nonrecourse Notes at the grant date using the following assumptions in the BSM option pricing model:

Risk-free interest rate	1.1%
Expected term (years)	5.86 years
Exercise price	$1.25
Expected dividend yield	0.0%
Expected volatility	37.6%
Grant date fair value	$0.40

The Company recognized $0.1 million and $2.5 million of stock-based compensation expense related to the restricted shares financed through Nonrecourse Notes discussed above for the years ended December 31, 2019 and 2020, which is included in general and administrative expense.

A summary of the Company's option activity related to common stock through restricted stock purchase agreements in exchange for Nonrecourse Notes during 2019 and 2020 was as follows:

	Number of Shares
Outstanding, January 1, 2019	2,924,130
Granted	—
Outstanding, December 31, 2019	2,924,130
Granted	7,373,163
Forgiveness of Nonrecourse Notes on vested shares of common stock	(425,000)
Outstanding, December 31, 2020	9,872,293
Vested, December 31, 2020	6,762,220

The total stock-based compensation expense was:

	2019	2020
Sales and marketing	$ —	$ 1
Research and development	45	98
General and administrative	291	3,064
Total stock-based compensation expense	$ 336	$ 3,163

Total unrecognized compensation expense as of December 31, 2019 and 2020 was $0.2 million and $1.7 million, respectively.

Early Exercise Liability

The unvested shares of the early-exercised options are held in escrow until the stock option becomes fully vested or until the employee's termination, whichever occurs first. The right to repurchase these shares lapses over the four-year vesting period. As of December 31, 2020, the early exercise liability was approximately $0.2 million and is included in accrued liabilities in the balance sheets. There were no early exercised options prior to 2020. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest.

The following table summarizes the activity of the unvested common stock issued pursuant to an early exercise of stock option awards during the year ended December 31, 2020:

	Number of Shares
Unvested at beginning of year	—
Early exercised stock options during period	855,000
Vested or cancelled	(538,334)
Unvested at end of year	316,666

NOTE 14. LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method and the if-converted method. Dilutive potential common shares include stock options, non-vested shares, redeemable convertible preferred shares, restricted stock and similar equity instruments granted by the Company. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

Basic and diluted net loss attributable to common holders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock, common stock subject to restricted stock purchase agreements, early exercised options, and restricted shares are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Accordingly, for the years ended December 31, 2019 and 2020, there is no difference in the number of shares used to calculate basic and diluted shares outstanding. For the year ended December 31, 2019, outstanding common stock for accounting purposes excludes 2,924,130 shares subject to restricted stock purchase agreements. For the year ended December 31, 2020, outstanding common stock for accounting purposes excludes 9,872,293 shares subject to restricted stock purchase agreements and 316,666 unvested early exercised stock options.

The table below presents the computation of basic and diluted earnings per share:

	2019	2020
Basic:		
Net loss attributable to common stockholders	$ (20,606)	$ (47,352)
Weighted-average common shares outstanding, basic and diluted	15,760,246	16,315,730
Net loss attributable to common stockholders per share, basic and diluted	$ (1.31)	$ (2.90)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	As of December 31,	
	2019	2020
Redeemable convertible preferred stock	54,527,458	83,526,065
Stock options	8,244,751	8,344,752
Early exercised options	—	316,666
Common stock subject to restricted stock purchase agreements	2,924,130	9,872,293
Common stock warrants	75,744	75,744
Redeemable convertible preferred stock warrants	79,882	79,882
Total	65,851,965	102,215,402

NOTE 15. INCOME TAXES

The Company recorded no federal or state income tax expense or benefit for the years ended December 31, 2019 and 2020 primarily as a result of the Company maintaining a full valuation allowance against its loss from operations for tax purposes. The net losses for the years ended December 31, 2019 and 2020 were generated solely in the United States.

The effective tax rate of the (benefit) provision for income taxes differs from the U.S. federal statutory rate as follows:

	Years Ended December 31,	
	2019	2020
Expected tax at the federal statutory rate	(21.0)%	(21.0)%
State income tax, net of federal benefit	(7.0)%	(7.6)%
Permanent items	0.9%	1.3%
Change in valuation allowance	30.9%	30.8%
Tax Credits	(4.8)%	(3.3)%
Uncertain tax position reserves	1.0%	0.7%
Stock-based compensation	—	(0.9)%
Provision for income taxes	—	—

The Company recorded a valuation allowance to reflect the estimated amount of certain U.S. federal and state deferred tax assets that, more likely than not, will not be realized. In making such a determination, the Company evaluates a variety of factors including the projected future taxable income, scheduled reversals of deferred tax liabilities, prudent tax planning strategies, and recent financial operations. The evaluation of this evidence requires significant judgement about the forecasts of future taxable income, based on the plans and estimates used to manage the underlying business. The net change in total valuation allowance for the years ended December 31, 2019 and 2020 was an increase of $5.9 million and an increase of $14.6 million, respectively. The 2019 and 2020 valuation allowance increases were both driven primarily by U.S. federal and state NOL carryforwards that are not expected on a more likely than not basis to be realized.

The significant components of deferred income taxes were as follows:

	As of December 31,	
	2019	2020
Deferred tax assets:		
Net operating losses	$ 15,755	$ 29,217
Research and development credits	2,541	3,791
Operating lease liability	—	3,234
Share-based compensation	231	350
Accruals	45	2,963
Other	772	226

	As of December 31,	
	2019	2020
Total deferred tax assets	19,344	39,781
Deferred tax liabilities:		
Operating right-of-use asset	—	(2,376)
Depreciation and amortization	(41)	(3,511)
Total deferred tax liabilities	(41)	(5,887)
Gross deferred tax assets	19,303	33,894
Less: Valuation allowance	(19,303)	(33,894)
Net deferred income taxes	$ —	$ —

At December 31, 2020, the Company has United States federal and state net operating loss ("NOL") carryforwards of $108.7 million and $90.8, respectively. The federal NOL carryforwards generated in pre-2018 tax years of $26.2 million will begin to expire in 2031 while federal NOLs generated after 2017 of $82.5 million will carry forward indefinitely. The state NOL carryforwards of $90.8 million will begin to expire in 2031 unless previously utilized. At December 31, 2020, the Company also had federal and California research tax credit carryforwards of $2.9 million and $2.3 million, respectively. The federal research tax credit carryforwards begin to expire in 2032, if not utilized, while the California research tax credit carries forward indefinitely.

The above NOL carryforward and the research tax credit carryforwards are subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code ("IRC") of 1986, and similar state provisions due to ownership change limitations that have occurred which will limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. The Company has completed a Section 382/383 analysis through December 31, 2020 and determined an ownership change, as defined under Section 382, occurred in 2014 and 2018. The resulting limitations have restricted the use of the Company's NOL and tax credit carryforwards. As of December 31, 2020, the Company has $30.1 million of federal net operating losses and $29.8 million of state NOLs subject to limitations related to the utilization under Section 382 of the Internal Revenue Code. As of December 31, 2020, the Company has $1.2 million of federal tax credit carryforwards and $1.2 million of state tax credit carryforwards subject to limitations related to the utilization under Section 383 of the Internal Revenue Code. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company's operations in the United States will not impact the Company's effective tax rate.

The Company recognizes the benefit of tax positions taken or expected to be taken in its tax returns in the financial statements when it is more likely than not that the position will be sustained upon examination by authorities. Recognized tax positions are measured at the largest amount of benefit that is greater than 50% likely of being realized upon settlement.

A reconciliation of the beginning and ending balance to total unrecognized tax position is as follows:

	Years Ended December 31,	
	2019	2020
Beginning balance	$ 489	$ 705
Increases related to current year tax positions	216	340
Ending Balance	$ 705	$ 1,045

As of December 31, 2020, the Company has approximately $1.0 million of unrecognized tax benefits, none of which would currently affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. As of December 31, 2019, and December 31, 2020, the Company recorded no accrued interest and penalties related to unrecognized tax benefits. The Company does not expect any significant changes in its tax positions that would warrant recognition of a liability for unrecognized income tax benefits during the next 12 months.

The Company's United States federal and state income tax returns are subject to tax examination by U.S. federal and state tax authorities for tax years within the statute of limitations. All tax carryforwards are subject to adjustment until the statute closes on the year the carryforwards are eventually utilized. The statute remains open on tax carryforwards generated and unutilized as of December 31, 2020 for the 2011 and subsequent tax years.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, H.R. 748 (CARES Act) was enacted and signed into law in the United States. The CARES Act includes modifications to the Internal Revenue Code and provides for relief to U.S. corporations through programs such as the employee retention credit, payroll tax deferral and modifications to certain income tax provisions such as temporary five-year net operating loss carryback provisions and a modification of interest deduction limitations. The CARES Act did not have a significant impact on the Company's financial statements for year ended December 31, 2020.

On June 29, 2020, Assembly Bill 85 ("AB 85") was signed into law as part of the California 2020 Budget Act and temporarily suspends the use of California net operating losses and imposes a cap on the amount of business incentive tax credits that companies can utilize against their taxable income for tax years 2020, 2021, and 2022. The Company evaluated the provisions of AB 85 and determined there was no impact on the provision for income taxes for the current period given the full valuation allowance against the California net operating loss and tax credit carryforwards. The Company will continue to evaluate the impact, if any, AB 85 may have on its financial statements and disclosures.

The Consolidated Appropriations Act, 2021, ("CAA") was signed into law on December 27, 2020. The CAA includes, among other provisions, tax and direct spending relief for businesses and individuals affected by the coronavirus pandemic; and extends dozens of expiring tax deductions, credits, and incentives. The Company evaluated the impact of the CAA and determined that it did not have a material impact to the income tax provision for the tax year ended December 31, 2020.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Product Liability

The Company's business exposes it to liability risks from its potential medical diagnostic products. Product liability claims could result in the payment of significant amounts of money and divert management's attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes it carries reasonably adequate insurance for product liability.

Standby Letters of Credit

The Company entered into letters of credit (LOCs) for a total of $7.7 million with Comerica Bank as collateral required by one of the Company's vendors and in lieu of three of its lease agreements. The LOCs are automatically extended for a period of one year from unless the Company provides a notice to terminate the agreements ranging from 30 to 90 days prior to the expiration date. The Company was required to reserve a cash balance of $0.2 million and $7.7 million at December 31, 2019 and December 31, 2020, respectively, as collateral for the LOCs, which are presented as restricted cash on the balance sheets.

NOTE 17. RETIREMENT PLAN

The Company maintains a defined contribution employee retirement plan which allows eligible employees, including named executive officers, to contribute pre-tax and Roth contributions to the plan, as allowed by law. The Company currently does not match employee contributions.

NOTE 18. SUBSEQUENT EVENTS

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that may require additional disclosure. The Company has completed an evaluation of all subsequent events through April 19, 2021, the date on which the financial statements were issued, during which time nothing has occurred outside the normal course of business operations that would require disclosure other than the events disclosed below.

Settlement of Contingency

In March 2021, the Company reached a settlement pursuant to a consulting agreement for services rendered during the year ended December 31, 2020, related to the advancement of the Company's diagnostic platform and identification of funding opportunities. The Company agreed to pay $9.0 million, payable in four equal installments over eighteen months, starting on April 1, 2021. This amount is included in the statements of operations in general and administrative expense for the year ended December 31, 2020. As of December 31, 2020, $4.5 million of this amount was included in accrued liabilities and $4.5 million was included in other non-current liabilities in the accompanying balance sheet.

Revolving Line of Credit

In February 2021, the Company entered a Loan and Security Agreement (the "Revolving Credit Agreement") with East West Bank, Comerica Bank, and Silicon Valley Bank (collectively, "Lenders") with East West Bank serving as the collateral and administrative agent for the Lenders ("Agent"). The Revolving Credit Agreement provides for a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit subfacility of $20.0 million.

Amounts under the Loan Agreement may be borrowed and repaid at any time without penalty or premium prior to the revolving maturity date of February 5, 2023, at which time all of the outstanding advances with all unpaid interest and fees will immediately be due and payable. The advances bear interest, on the outstanding daily balance thereof, at a rate equal to 0.75% above the prime rate but in no event shall the interest rate be less than 4.0%.

The Revolving Credit Agreement includes customary representations, warranties and negative and affirmative covenants of the company, as well as customary events of default. Subject to certain qualifications and exceptions, the agreement will, among other things, limit the ability to: incur or guaranty additional indebtedness; create or permit liens on the Company's assets; pay dividends or distributions; make certain investments; make certain fundamental changes, assets dispositions and acquisitions; and engage in certain transactions with shareholders and affiliates. In addition, the Revolving Credit Agreement requires the Company to maintain a minimum asset coverage ratio of 1.25 to 1.00, minimum remaining months liquidity of at least six months, and minimum liquidity of at least $80.0 million. The obligations under the Revolving Credit Agreement are secured by substantially all of the Company's assets.

Leases

In January 2021, the Company entered into a lease agreement for approximately 8,010 square feet in an industrial building in San Diego, California. The initial lease term is three years. The future minimum rent commitment is approximately $1.0 million.

Cue Health Inc.

CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands, except share data)

	December 31, 2020	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$121,578	$246,326
Restricted cash	6,000	6,000
Accounts receivable	4,168	40,277
Inventory	36,842	63,263
Prepaid expenses	13,847	35,784
Other current assets	1,263	827
Total current assets	183,698	392,477
Restricted cash, non-current	1,677	—
Property and equipment, net	103,683	160,182
Prepaid rent	16,771	1,648
Operating lease right-of-use assets	8,281	69,511
Intangible assets, net	2,038	2,728
Other non-current assets	180	4,766
Total assets	$316,328	$631,312
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 23,847	$ 25,824
Accrued liabilities and other current liabilities	8,822	34,424
Deferred revenue, current	115,747	93,745
Debt, current	5,434	—
Operating lease liabilities, current	797	3,170
Finance lease liabilities, current	1,249	1,349
Total current liabilities	155,896	158,512
Redeemable convertible preferred stock warrant liabilities	1,331	1,521
Deferred revenue, net of current portion	67,349	46,748
Convertible notes	—	258,734
Operating leases liabilities, net of current portion	10,472	46,274
Finance lease liabilities, net of current portion	1,857	1,694
Other non-current liabilities	4,500	2,838
Total liabilities	241,405	516,321
Commitments and contingencies (Note 16)		
Redeemable Convertible Preferred Stock		
Series A redeemable convertible preferred stock, $0.00001 par value; 8,721,437 shares authorized, 8,350,743 issued and outstanding at December 31, 2020 and June 30, 2021; liquidation preference of $7,660 at December 31, 2020 and June 30, 2021	7,519	7,519
Series B redeemable convertible preferred stock, $0.00001 par value; 46,213,620 shares authorized, 46,176,715 issued and outstanding at December 31, 2020 and June 30, 2021; liquidation preference of $66,240 at December 31, 2020 and June 30, 2021	66,186	66,186

The accompanying notes are an integral part of these condensed financial statements.

	December 31, 2020	June 30, 2021
Series C-1 redeemable convertible preferred stock, $0.00001 par value; 27,308,229 shares authorized, 27,308,227 issued and outstanding at December 31, 2020 and June 30, 2021, respectively; liquidation preference of $100,000 at December 31, 2020 and June 30, 2021	96,436	96,436
Series C-2 redeemable convertible preferred stock, $0.00001 par value; 1,690,380 shares authorized, issued and outstanding at December 31, 2020 and June 30, 2021; liquidation preference of $5,571 at December 31, 2020 and June 30, 2021	6,182	6,182
Total redeemable convertible preferred stock	176,323	176,323
Stockholders' Deficit		
Common stock, $0.00001 par value; 129,030,355 shares authorized, 27,995,780 and 29,128,604 issued and outstanding at December 31, 2020 and June 30, 2021, respectively	—	—
Additional paid-in-capital	9,036	16,264
Accumulated deficit	(110,436)	(77,596)
Total stockholders' deficit	(101,400)	(61,332)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 316,328	$631,312

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share data)

	Six Months Ended June 30,	
	2020	**2021**
Revenue		
Product revenue	$ —	$ 201,922
Grant and other revenue	4,960	—
Total revenue	4,960	201,922
Operating costs and expenses:		
Cost of product revenue	—	85,177
Sales and marketing	45	1,959
Research and development	19,680	12,071
General and administrative	3,764	23,252
Total operating costs and expenses	23,489	122,459
Income (loss) from operations	(18,529)	79,463
Interest expense	(788)	(9,964)
Change in fair value of redeemable convertible preferred stock warrants	(20)	(190)
Change in fair value of convertible notes	—	(23,254)
Other income (expense), net	59	61
Net income (loss) before income taxes	(19,278)	46,116
Income tax expense	—	(13,276)
Net income (loss)	$ (19,278)	$ 32,840
Basic net income (loss) per share attributable to common stockholders	$ (1.21)	$ 0.23
Weighted-average number of shares used in computation of basic net income (loss) per share attributable to common stockholders	15,909,439	18,617,247
Diluted net income (loss) per share attributable to common stockholders	$ (1.21)	$ 0.22
Weighted-average number of shares used in computation of diluted net income (loss) per share attributable to common stockholders	15,909,439	26,036,337

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(Unaudited)
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	8,350,743	$7,519	46,176,715	$66,186	—	$ —	18,704,118	$—	$4,945	$(63,084)	$(58,139)
Issuance of Series C-1 preferred stock	—	—	—	—	27,308,227	96,963	—	—	—	—	—
Conversion of convertible notes to Series C-2 preferred stock	—	—	—	—	1,690,380	6,182	—	—	—	—	—
Exercise of common stock options	—	—	—	—	—	—	1,520,000	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	729	—	729
Stock-based compensation	—	—	—	—	—	—	—	—	97	—	97
Net loss	—	—	—	—	—	—	—	—	—	(19,278)	(19,278)
Balance at June 30, 2020	8,350,743	$7,519	46,176,715	$66,186	28,998,607	$103,145	20,224,118	$—	$5,771	$(82,362)	$(76,591)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	8,350,743	$7,519	46,176,715	$66,186	28,998,607	$102,618	27,995,780	$—	$ 9,036	$(110,436)	$(101,400)
Exercise of common stock options	—	—	—	—	—	—	1,048,706	—	258	—	258
Stock-based compensation expense from issuance of a fully vested warrant to vendor	—	—	—	—	—	—	—	—	1,239	—	1,239
Exercise of common stock warrant	—	—	—	—	—	—	84,118	—	77	—	77
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	63	—	63
Stock-based compensation	—	—	—	—	—	—	—	—	5,591	—	5,591
Net income	—	—	—	—	—	—	—	—	—	32,840	32,840
Balance at June 30, 2021	8,350,743	$7,519	46,176,715	$66,186	28,998,607	$102,618	29,128,604	$—	$16,264	$ (77,596)	$ (61,332)

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2020	**2021**
Cash flows from operating activities		
Net income (loss)	$ (19,278)	$ 32,840
Adjustments to reconcile net income (loss) to net cash, cash equivalents and restricted cash used in operations		
Depreciation and amortization	3,399	14,500
Inventory reserve	—	353
Change in fair value of redeemable convertible preferred stock warrant liabilities	20	190
Change in fair value of convertible notes	—	23,254
Stock-based compensation expense	97	5,591
Loss on extinguishment of debt	610	1,998
Non-cash lease expense	277	1,822
Amortization of debt issuance costs	16	130
Convertible notes issuance costs	—	6,000
Deferred income taxes	—	588
Interest on finance leases	39	100
Stock-based compensation expense from issuance of fully vested warrant to vendor	—	1,239
Changes in operating assets and liabilities:		
Accounts receivable	(2,579)	(36,109)
Inventory	(664)	(26,774)
Prepaid expenses and other current assets	(4,684)	(22,818)
Other non-current assets	—	(676)
Accounts payable, accrued liabilities and other current liabilities	1,741	11,473
Deferred revenue	—	(42,602)
Operating lease liabilities	51	(8,911)
Net cash, cash equivalents and restricted cash used in operating activities	(20,955)	(37,812)
Cash flows from investing activities		
Purchase of property and equipment	(1,326)	(56,545)
Expenditures for software development	—	(2,351)
Net cash, cash equivalents and restricted cash used in investing activities	(1,326)	(58,896)
Cash flows from financing activities		
Proceeds for Series C-1 redeemable convertible preferred stock	100,000	—
Proceeds from convertible notes	5,563	235,480
Payments for issuance costs of Series C redeemable convertible preferred stock	(3,037)	—
Payments of issuance costs of convertible notes	—	(6,000)
Proceeds from exercise of common stock options	729	258
Proceeds from exercise of common stock warrant	—	77
Proceeds from debt	—	82,250
Debt issuance and prepayment costs	—	(2,128)
Repayment of debt	(1,286)	(87,684)
Payments for deferred initial public offering costs	—	(1,610)
Payments for finance leases	(246)	(864)
Net cash, cash equivalents and restricted cash provided by financing activities	101,723	219,779

The accompanying notes are an integral part of these condensed financial statements.

	Six Months Ended June 30,	
	2020	2021
Net increase in cash, cash equivalents and restricted cash	79,442	123,071
Cash, cash equivalents and restricted cash, beginning balance	14,505	129,255
Cash, cash equivalents and restricted cash, ending balance	$93,947	$252,326
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$92,270	$246,326
Restricted cash, current	—	6,000
Restricted cash, non-current	1,677	—
Total cash, cash equivalents and restricted cash	$93,947	$252,326
Supplemental disclosure for cash flow information		
Cash paid for interest	$ 72	$ 760
Supplemental disclosure for non-cash investing and financing matters		
Early exercised stock options liability	$ —	$ 63
Right-of-use assets obtained in exchange for lease obligations	$ 8,849	$ 38,717
Prepaid rent reclassified to right-of-use assets	$ —	$ 15,966
Purchase of property and equipment included in accounts payable	$ 393	$ 11,618
Deferred initial public offering costs included in accounts payable and accrued liabilities and other current liabilities	$ —	$ 2,301

The accompanying notes are an integral part of these condensed financial statements.

Cue Health Inc.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share data)

NOTE 1. BUSINESS AND BASIS OF ACCOUNTING

Organization and Description of Business

Cue Health Inc. (the "Company") was originally formed in the State of California on January 26, 2010, prior to being incorporated in the State of Delaware on December 14, 2017. The Company is a healthcare technology company committed to revolutionizing the healthcare experience by providing individuals with a convenient and connected diagnostic platform that bridges the physical and virtual care continuum. The Company's proprietary platform, the Cue Health Monitoring System, comprised of the Cue Reader and Cue Test Kit, enables lab-quality diagnostics-led care at home, at work or at the point of care. This platform is designed to empower stakeholders across the healthcare ecosystem, including individuals, enterprises, healthcare providers and payors, and public health agencies with paradigm-shifting access to diagnostic and health data to inform care decisions. The Company's headquarters are located in San Diego, California.

Liquidity and Capital Resources

As of June 30, 2021, the Company has cash, cash equivalents and restricted cash of $252.3 million. Management believes that the current available cash and cash equivalents will be sufficient to fund the Company's planned expenditures and meet its obligations for at least twelve months following the financial statement issuance date.

Basis of Presentation

The accompanying unaudited interim condensed financial statements should be read in conjunction with the audited annual financial statements and notes thereto for the year ended December 31, 2020. The unaudited interim condensed balance sheet as of December 31, 2020 included herein was derived from the audited financial statements as of that date. The results of operations for the six months ended June 30, 2021 and cash flows for the six months ended June 30, 2021 are not necessarily indicative of the results for the fiscal year ending December 31, 2021 or any future interim period. The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting and, in the opinion of management, include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All such adjustments are of a normal, recurring nature. Certain disclosures have been condensed or omitted from the interim condensed financial statements. The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, income and expenses as well as the related disclosure of contingent assets and liabilities.

Use of Estimates

The preparation of the accompanying financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates.

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, the fair value of the Company's common and redeemable convertible preferred stock warrants, the fair value of including the fair value of convertible notes, equity-based compensation expense, product warranty reserve, the recoverability of its long-lived assets and net deferred tax assets (and related valuation allowance). The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

COVID-19 Impact

The novel coronavirus ("COVID-19") that was declared a global pandemic by the World Health Organization in March 2020 adversely impacted global commercial activity but served as a catalyst to accelerating the Company's product pipeline. The Company's first commercially available diagnostic test for the Cue Health Monitoring System

is the Cue COVID-19 test for ribonucleic acid of SARS-CoV-2, the virus that causes COVID-19. The Company began selling and recording product revenue for its Cue COVID-19 test in August 2020 after obtaining an Emergency Use Authorization ("EUA") from the Federal Drug Administration ("FDA") in June 2020. Currently, 100% of the Company's revenue is derived from the Cue COVID-19 test. Given the unpredictable nature of the COVID-19 pandemic, the development and potential size of the COVID-19 diagnostic testing market is highly uncertain.

The FDA issued emergency use authorizations for two COVID-19 vaccines and in February 2021, the FDA issued a third EUA for a COVID-19 vaccine. The widely administered use of an efficacious vaccine or new therapeutic treatment for COVID-19 may reduce the demand for the Cue COVID-19 test and, as a result, the COVID-19 diagnostic testing market may not develop or grow substantially. Given the rapid development of events surrounding the pandemic, there is uncertainty to the Company's future results and performance.

NOTE 2. SIGNIFICANT ACCOUNTING POLICIES AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

Significant Accounting Policies

During the six months ended June 30, 2021, there have been no changes to our significant accounting policies as described in our audited annual financial statements for the year ended December 31, 2020, except as noted below.

Fair Value Measurements and Financial Instruments

The carrying value of the Company's cash and cash equivalents, accounts receivables and accounts payable approximate fair value due to the short-term nature of these items. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the Company's long-term borrowings approximates its fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company's redeemable convertible preferred stock warrant liabilities and convertible notes are measured at fair value on a recurring basis and are classified as Level 3 liabilities. The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date in current period earnings.

Convertible Notes

The Company elected to account for convertible notes issued in May 2021 using the fair value option. Such instruments are recognized at estimated fair value, with changes in estimated fair value recorded as a component of earnings in the statements of operations unless the change is a result of a change in credit risk, in which case such change in estimated fair value is recorded within other comprehensive income. Direct issuance costs are expensed as incurred and are included in interest expense in the statements of operations.

Increases or decreases in the fair value of the convertible notes can result from updates to assumptions such as the expected timing or probability of a qualified financing event, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on the Company's results of operations in any given period.

Revenue Recognition

Department of Defense Contract Waiver

Per the terms of the U.S. DoD Agreement entered into in October 2020, the Company was required to deliver to the U.S government all of its manufacturing output of Cue COVID-19 Cartridges, subject to certain exceptions for existing contracts and for future contracts the Company is able to obtain waivers for from the U.S. government.

In April 2021, the Company was granted a waiver by the U.S. government to distribute up to 50% of the entire production of the Cue COVID-19 Test to commercial customers, measured monthly in arrears on a calendar-month basis. The waiver became effective in May 2021 and is applicable to the Company's production of Cue COVID-19 Tests during April 2021.

The waiver will remain in effect for the duration of the U.S. DoD Agreement; however, the U.S. government may modify the waiver to reasonably accommodate changes in U.S. government requirements. To modify the waiver, the U.S. government must submit a written notice to the Company specifying the increase or decrease in the percentage of the Cue COVID-19 Test production that may be distributed to commercial customers and the effective date of the modification.

New Revenue Contracts

In the second quarter of 2021, the Company entered into a purchase agreement to provide a customer with Cue Health Readers and in excess of 1,000,000 Cue Test Kits between the effective date of the agreement and December 2021 based on a pre-defined monthly delivery schedule. In the third quarter of 2021, the customer increased its order of Cue Health Readers and Cue COVID-19 Test Kits. The customer may change the quantities ordered and may terminate the order and/or agreement with a 45 days' notice.

In May 2021, the Company entered into a purchase agreement to provide a customer a one-time order of 1,000 Cue Health Readers and 300,000 Cue COVID-19 Test Kits on a monthly basis during the 12-month period following the agreement execution date. In August 2021, the Company and customer amended the purchase agreement to reduce the number of Cue COVID-19 Test Kits to 10,000 test kits on a monthly basis until the agreement expiration date. The agreement may be terminated for cause by either party with a 30 days' notice.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the equity financing. If a planned equity financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed statements of operations. There were $0 and $3.9 million of deferred offering costs recorded in the Company's balance sheets in other non-current assets as of December 31, 2020, and June 30, 2021, respectively.

Product Warranty Reserve

The Company provides its customers with the right to receive a replacement of defective or nonconforming Cue Readers for a period of up to twelve months from the date of shipment. Although no explicit warranty is provided for Cue Cartridges, the Company may replace Cue Cartridges that result in invalid test results. Provisions for estimated expenses related to product warranty are made at the time products are sold. These estimates are determined using historical information that include test failure rates, replacement frequency, and the overall replacement cost.

(In thousands, except share data)

The Company evaluates the reserve on a quarterly basis and makes adjustments when appropriate. Changes to test failure rates and overall replacement rates could have a material impact on our estimated liability. The product warranty reserve is recorded within accrued liabilities and other current liabilities on the balance sheets and in cost of product revenue in the statements of operations.

The following table provides a reconciliation of the change in estimated warranty liabilities:

	Amount
Balance, December 31, 2020	$ —
Provision for warranties	4,611
Settlements	(101)
Change in warranty estimates	—
Balance, June 30, 2021	$4,510

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies the accounting for income taxes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020 for public companies and for fiscal years beginning after December 15, 2021 for all other entities and early adoption is permitted. The Company adopted ASU 2019-12 on January 1, 2021 on a prospective basis. The adoption did not have an impact on the Company's financial statements.

NOTE 3. REVENUE

Product Revenue

The Company generates revenue from the sale of its Cue Health Monitoring System to public sector entities, healthcare providers, commercial customers, and through agreements with distributors. The Cue Health Monitoring System is comprised of the Cue Reader and the Cue Test Kit composed of the Cue Cartridge and Cue Wand. The Cue Health App is integral to the functionality of the Cue Reader and these components form a single performance obligation. Customers also have the option to use the Cue Enterprise Dashboard which provides allows customers to view historical test results within their organization.

The Company considers purchase orders, which are governed by agreements with customers, to be a contract with a customer. The contract terms with customers range in length, from one-time purchases, six-month commitments or twelve-month commitments. The timing of revenue recognition is based on the satisfaction of performance obligations promised to the customer. Revenue allocated to Cue Readers and Cue Test Kits is recognized when control of the promised goods has transferred to customers, generally upon shipment, in an amount that reflects the consideration the Company expects to receive in exchange for those goods. Revenue for the for the Cue Enterprise Dashboard is recognized ratably over the term of the service but has not been material to date.

For the six months ended June 30, 2021, product revenue primarily relates to a $480.9 million agreement ("U.S. DoD Contract") the Company entered into with the U.S. government for the purchase of its Cue COVID-19 Test. The U.S. DoD Agreement provided $184.6 million to facilitate the scaling of the Company's manufacturing capacity, which was received upon signing the contract ("U.S. DoD Advance"). The remainder of the agreement is for the sale of the Company's products. There was no product revenue generated during the six months ended June 30, 2020.

During the six months June 30, 2021, the Company entered into two agreements with commercial customers to deliver Cue Test Kits on a pre-defined monthly delivery schedule over the course of up to twelve months.

Cue Health Inc.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share data)

Disaggregation of the product revenue by type of customer for the six months ended June 30, 2020, and 2021, respectively:

	Six Months Ended June 30,	
	2020	2021
Public sector entities	$—	$167,120
Other customers	—	34,802
Total product revenue	$—	$201,922

Product revenue from public sector entities primarily relates to the U.S. DoD Contract.

The following table sets forth the Company's product gross profit and product gross profit margin for the six months ended June 30, 2020 and 2021:

	Six Months Ended June 30,	
	2020	2021
Product revenue	$—	$201,922
Cost of product revenue	—	85,177
Product gross profit	$—	$116,745
Product gross profit margin	0%	58%

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for work completed but not billed at the reporting date. The contract assets balance as of December 31, 2020 and June 30, 2021, as well as changes in the balance during the period, were not material.

Contract liabilities primarily relate to the U.S. DoD Advance and were recorded in current and non-current deferred revenue on the balance sheets. The activity related to contract liabilities for the six months ended June 30, 2021 is as follows:

	Amount
Balance, December 31, 2020	$183,096
Recognition of U.S. DoD Advance	(42,208)
Recognition of non-refundable customer deposits	(395)
Balance, June 30, 2021	$140,493

Grant and Other Revenue

Grant and other revenue relate to a cost reimbursement agreement with the Biomedical Advanced Research and Development Authority ("BARDA") and a collaboration agreement with Janssen Pharmaceuticals, Inc. ("Janssen"). During the six months ended June 30, 2020, all of the revenue recognized related to the agreement with BARDA. There was no activity related to this revenue category during the six months ended June 30, 2021.

Cue Health Inc.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)
(In thousands, except share data)

NOTE 4. INVENTORIES

As of December 31, 2020, and June 30, 2021, the Company's inventories consisted of the following:

	December 31, 2020	June 30, 2021
Raw materials	$29,948	$36,715
Work-in-process	4,957	12,312
Finished goods	1,645	14,600
Inventory on consignment	1,081	1,106
Reserve	(789)	(1,470)
Total inventories	$36,842	$63,263

Inventory on consignment represents inventory owned by the Company that is on hand with contract manufacturers. The inventory reserve relates excess and obsolete inventory as a result of ongoing assessments of inventory on hand and the continuous improvement and innovation of its products. During the six months ended June 30, 2021, $10.5 million of capitalized depreciation and amortization costs were expensed to cost of product revenue as inventory was sold. As of June 30, 2021, $2.9 million of capitalized depreciation and amortization costs were part of the inventory balance.

NOTE 5. PREPAID EXPENSES

As of December 31, 2020, and June 30, 2021, the Company's prepaid expenses consisted of the following:

	December 31, 2020	June 30, 2021
Prepaid expenses	$ 5,152	$13,834
Prepaid inventory	8,695	21,950
Total prepaid expenses	$13,847	$35,784

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of December 31, 2020, and June 30, 2021, the Company's property and equipment, net consisted of the following:

	December 31, 2020	June 30, 2021
Construction in progress	$ 83,353	$ 38,467
Machinery and equipment	26,972	129,083
Leasehold improvements	2,897	15,872
Furniture and fixtures	683	750
Property and equipment	113,905	184,172
Accumulated depreciation and amortization	(10,222)	(23,990)
Total property and equipment, net	$103,683	$160,182

Depreciation and amortization expense related to property and equipment was $12.8 million for the six months ended June 30, 2021. During the six months ended June 30, 2021 $11.9 million of depreciation and amortization expense was capitalized into inventory during the manufacturing process. The carrying value of assets under finance leases within property and equipment as of December 31, 2020 and June 30, 2021 was $4.8 million and $5.5 million, respectively.

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NOTE 7. INTANGIBLE ASSETS

As of December 31, 2020, and June 30, 2021, the Company's intangible assets consisted of the following:

	December 31, 2020	June 30, 2021
Capitalized software	$2,114	$ 4,465
Accumulated amortization	(76)	(1,737)
Total intangible assets	$2,038	$ 2,728

Amortization expense related to intangible assets for the six months ended June 30, 2020 was not material and was $1.7 million for the six months ended June 30, 2021. Estimated amortization expense for each of the years ending December 31 is as follows:

2021 (excluding the six months ended June 30, 2021)	$ 509
2022	1,018
2023	970
2024	231
Total amortization expense	$2,728

During the six months ended June 30, 2021, the Company identified certain immaterial amounts that should not have been capitalized as intangible assets. These amounts were recorded as incremental amortization expense during the six months ended June 30, 2021.

NOTE 8. LEASES

In June 2020, the company entered into an agreement to lease a 63,700 square-foot building to be used as manufacturing facility in San Diego, California ("Waples Lease"). The Waples lease has an initial term of ten years with a renewal option to extend the lease which the company is not reasonably certain to exercise. The Waples Lease commenced in May 2021 when the Company was granted a temporary certificate of occupancy to install the manufacturing equipment. The Company paid $12.5 million for landlord-owned improvements sitting as a prepaid rent until the commencement date when those were reclassified into the right-of-use asset. The Company recognized a total operating lease right-of use asset of approximately $32.4 million and operating lease liabilities of $19.9 million related to the Waples Lease as of commencement date.

In October 2020, the Company entered into an agreement to lease a 197,000 square-foot building to be used as a manufacturing facility in Vista, California ("Vista Lease"). The Vista Lease has an initial term of five years and the company is reasonably certain to exercise a renewal option to extend the lease term for an additional five years. The Vista Lease commenced in January 2021 when the Company was permitted to install its tenant improvements and manufacturing equipment. The Company recognized an operating lease right-of use asset of approximately $20.5 million and operating lease liabilities of $17.1 million related to the Vista Lease as of commencement date.

Subsequent to the commencement dates of the Waples and Vista leases, the Company made cash payments of $9.1 million related to the ongoing construction of landlord-owned assets. This is presented in operating lease liabilities in the statements of cash flows.

In January 2021, the Company entered into a lease agreement for approximately 8,010 square feet in an industrial building in San Diego, California. The initial lease term is three years without any renewal option. The lease commenced in February 2021 when the Company was permitted to install the tenant improvements. This lease was classified as operating lease and recognized in the right of use asset and liability during the period.

The Company made payments of $1.6 million related to deposits for equipment leases that had not commenced as of June 30, 2021. The payments have been capitalized in prepaid rent and will be reflected in right-of-use assets upon commencement of the leases.

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The right-of-use assets and lease liabilities recognized on the Company's balance sheet as of June 30, 2021 were as follows:

		June 30, 2021	
	Balance Sheet Location	Operating Leases	Finance Leases
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$69,511	
Right-of-use assets finance leases	*Property and equipment, net*		$5,456
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	3,170	
Finance lease liabilities (current)	*Finance lease liabilities, current*		1,349
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	46,274	
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*		1,694

The components of lease expense for the six months ended June 30, 2020 and 2021 were as follows:

	Six Months Ended June 30,	
	2020	2021
Operating lease cost	$766	$2,967
Finance lease cost:		
Amortization of right-of-use assets	144	706
Interest on lease liabilities	39	100
Total lease cost	$949	$3,773

NOTE 9. CONVERTIBLE NOTES

In May 2021, the Company issued and sold convertible promissory notes ("Convertible Notes") with a principal amount of $235.5 million and incurred $6.0 million of debt issuance costs that have been recorded in interest expense in the statements of operations. The Convertible Notes accrue interest at a simple rate of 3.0% per annum during the first 12-month period and will accrue at a simple rate of 9.0% per annum thereafter.

The Convertible Notes are only convertible upon a qualified conversion event or a corporate transaction.

The Convertible Notes will be converted into shares of the Company's common stock at the then effective conversion price in the case of a qualified going public transaction: (a) an IPO resulting in at least $50 million in proceeds, (b) a SPAC combination, or (c) a direct listing. If the Company closes an equity financing with gross proceeds of not less than $50.0 million, then the Convertible Notes, unless previously converted into shares of our common stock, will automatically convert into shares of the same class and series of capital stock of the Company issued to investors in such equity financing. The conversion price with respect to a qualified conversion event, which would be a qualified going public transaction or an equity financing, will incorporate the applicable discount: (i) a 20.0% discount if the qualified conversion event is consummated on or prior to September 30, 2021, and (ii) a 25.0% discount if the qualified conversion event is consummated after September 30, 2021.

In the event of certain corporate transactions prior to the conversion of the Convertible Notes or the repayment of the Convertible Notes, each purchaser, in its discretion, shall have the right either (a) to convert, effective immediately prior to the closing of the corporate transaction, all, but not less than all, of the outstanding principal amount of a Convertible Note and all accrued and unpaid interest on such May 2021 Note immediately prior to the closing of a corporate transaction into shares of common stock at the then effective conversion price, or (b) be paid an amount equal to the sum of 1.75 times the outstanding principal amount of a Convertible Notes and all accrued and unpaid interest of such Convertible Notes immediately prior to the closing of a corporate transaction.

The Convertible Notes include customary events of default. In the event of any default under the Convertible Notes, the interest rate then in effect shall be increased by 3.0%, and then by an additional 3.0% each year thereafter, so long as such event of default continues. Unless earlier converted immediately prior to the qualified conversion event, the Convertible Notes and any unpaid accrued interest will become due in May 2023.

The Company elected to account for the Convertible Notes at estimated fair value pursuant to the fair value option and records the change in estimated fair value in the statement of operations. As of June 30, 2021, the fair value of the of the Convertible Notes was $258.7 million, and the Company recorded a loss of $23.3 million related to the change in estimated fair value of the Convertible Notes in its statement of operations for the six months ended June 30, 2021.

NOTE 10. DEBT

On February 5, 2021, the Company entered into a Loan and Security Agreement, or the Revolving Credit Agreement, with the lenders from time to time party thereto and East West Bank, as Administrative Agent and Collateral Agent for the lenders. In connection with entering into the Revolving Credit Agreement, the Company repaid outstanding amounts of $5.4 million and terminated the prior Loan and Security Agreement with Comerica Bank, or the 2015 Credit Agreement, that was initially entered into in May 2015. The 2015 Credit Agreement, as amended, provided for a revolving line with a credit extension of up to $4.0 million and a Growth Capital A Line with a credit extension of up to $6.0 million.

The Revolving Credit Agreement provides for a revolving credit facility with an aggregate maximum principal amount of $130.0 million and a letter of credit subfacility of $20.0 million. Availability under the Revolving Credit Agreement is subject to a minimum asset coverage test of 1.25 to 1.00, measured as the ratio of the sum of cash on hand maintained in the deposit accounts with the collateral agent and 50% of eligible accounts of the company to the aggregate amount of the outstanding obligations under the Revolving Credit Agreement.

Amounts under the Revolving Credit Agreement may be borrowed and repaid at any time without penalty or premium prior to the revolving maturity date of February 5, 2023, at which time all of the outstanding advances with all unpaid interest and fees will immediately be due and payable. The advances bear interest, on the outstanding daily balance thereof, at a rate equal to 0.75% above the prime rate but in no event shall the interest rate be less than 4.0%. The Company is required to pay a fee for unused amounts under the Revolving Credit Agreement in an amount equal to 0.25% of the unused portion of the revolving commitment. In the event that the Company terminates or permanently reduces the revolving commitment, in whole or in part, at any time before the revolving maturity date, the Company will be required to pay a fee equal to 1.00% of the amount by which the revolving commitment is permanently reduced, or the amount of the outstanding revolving commitment if terminated in full.

The Revolving Credit Agreement includes customary representations, warranties and negative and affirmative covenants of the Company, as well as customary events of default. Subject to certain qualifications and exceptions, the agreement will, among other things, limit the ability to: incur or guaranty additional indebtedness; create or permit liens on its assets; pay dividends or distributions; make certain investments; make certain fundamental changes, assets dispositions and acquisitions; and engage in certain transactions with shareholders and affiliates. In addition, the Revolving Credit Agreement requires the Company to maintain a minimum asset coverage ratio of 1.25 to 1.00, minimum remaining months liquidity of at least six months, and minimum liquidity of at least $80.0 million which is required to be held in deposit at East West Bank. The obligations under the Revolving Credit Agreement are secured by substantially all of the Company’s assets.

In May 2021, the Company repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the net proceeds from the issuance and sale of the Convertible Notes. In June 2021, the Company terminated the Revolving Credit Agreement and was required to pay a fee of $1.3 million, equal to 1.00% of the amount of the outstanding revolving commitment. The Company also wrote-off issuance costs of $0.7 million for a total loss on extinguishment of debt of $2.0 million. These amounts were recorded in interest expense in the

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statements of operations during the six months ended June 30, 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding letter of credit in the amount of $6.0 million, which has been cash collateralized. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

NOTE 11. WARRANTS

Common Stock Warrants

As of June 30, 2021, the Company had an outstanding warrant to purchase 75,744 shares of common stock at a purchase price of $0.40 per share. The warrant was issued on August 22, 2017 and expires on August 22, 2027. The warrant will automatically convert upon a change in control of the Company or a liquidation event. All shares subject to the warrant have vested as of June 30, 2021.

In May 2021, the Company issued a warrant to purchase 84,118 shares of common stock at a purchase price of $0.92 per share. The warrant was exercised in June 2021. The Company recorded an expense of $1.2 million in research and development expenses.

Redeemable Convertible Preferred Stock Warrants

Outstanding warrants to purchase redeemable convertible preferred shares as of June 30, 2021 was as follows:

	Shares	Exercise Price	Issuance Date	Expiration Date
Series A redeemable convertible preferred stock warrants	20,441	$0.91728	May 28, 2015	May 28, 2025
Series A redeemable convertible preferred stock warrants	20,441	0.91728	May 28, 2015	May 28, 2025
Series A redeemable convertible preferred stock warrants	7,631	0.91728	September 6, 2018	September 6, 2028
Series B redeemable convertible preferred stock warrants	31,369	1.4345	November 27, 2018	November 27, 2028

The redeemable convertible preferred stock warrants are classified as liabilities, with changes in fair value recorded through earnings, as the underlying redeemable convertible preferred shares can be redeemed by the holders of these shares upon the occurrence of certain events that are outside of the control of the Company. The Company estimated the fair value of the redeemable convertible preferred stock warrants using an option pricing model. The significant inputs to this valuation methodology included the rights, preferences and privileges of each class of Company's shares (see Note 12, *Fair Value Measurements*), and the Company's estimated equity value and volatility assumptions on the valuation date, which are based on management's analysis of comparable publicly traded peer companies.

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NOTE 12. FAIR VALUE MEASUREMENTS

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis within the fair value hierarchy as of December 31, 2020 and June 30, 2021:

December 31, 2020	Recurring Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Redeemable convertible preferred stock warrant liabilities	$—	$—	$1,331	$1,331

June 30, 2021	Recurring Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Redeemable convertible preferred stock warrant liabilities	$—	$—	$ 1,521	$ 1,521
Convertible Notes	$—	$—	$258,734	$258,734

There were no transfers between Level 1, Level 2 and Level 3 categories of the fair value hierarchy during the six months ended June 30, 2020 and 2021.

In May 2021, the Company issued and sold Convertible Notes with a principal amount of $235.5 million (See Note 9, *Convertible Notes*). The Company elected the fair value option to account for the Convertible Notes and recognized their estimated fair value, with changes in estimated fair value recorded as a component of earnings in the statements of operations. The fair value of the notes was determined based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy.

The Convertible Notes were valued using a scenario-based analysis. Three primary scenarios were considered and assigned a probability weighted to arrive at the estimated fair value. The first scenario considered the value impact of conversion at the 20.0% discount to the issue price if the Company had a qualified conversion event of (a) an IPO, (b) a SPAC combination, (c) or a direct listing, or (d) an equity financing with gross proceeds of not less than $50.0 million, before or on September 30, 2021. The second scenario considered the value impact of conversion at the 25.0% discount to the issue price if the Company had a qualified conversion event of (a) an IPO, (b) a SPAC combination, (c) or a direct listing, or (d) an equity financing with gross proceeds of not less than $50.0 million, after September 30, 2021. The third scenario assumed that a qualified conversion event did not occur, and the Convertible Notes and any unpaid accrued interest are repaid in May 2023.

The following table summarizes the significant unobservable inputs used in the fair value measurement of the Convertible Notes as of June 30, 2021:

	Conversion Event	Delayed Conversion Event	Repayment at Maturity
Expected event date	September 30, 2021	December 30, 2021	May 6, 2023
Term (years)	0.25	0.50	1.85
Discount rate	44.1%	44.1%	44.1%
Probability	90%	5%	5%

The Company recorded a loss of $23.3 million related to changes in the estimated fair value of the Convertible Notes in the statements of operations for the six months ended June 30, 2021. No material change to the credit risk of the Convertible Notes has occurred since the notes have been outstanding. As such, there was no impact on comprehensive income for the six months ended June 30, 2021.

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The following table provides a rollforward of the fair value of the Company's convertible notes and redeemable convertible preferred stock warrant liabilities measured on a recurring basis and classified within Level 3 fair value hierarchy:

	Redeemable Convertible Preferred Stock Warrants	Convertible Notes
Balance, December 31, 2020	$1,331	$ —
Issuance	—	235,480
Remeasurement	190	23,254
Balance, June 30, 2021	$1,521	$258,734

The estimated fair value of redeemable convertible preferred stock warrants was determined using BSM option pricing model with the following assumptions at December 31, 2020 and June 30, 2021:

Series A redeemable convertible preferred stock warrants

	December 31, 2020	June 30, 2021
Expected volatility	59.9%	70.5%
Expected term (years)	4.92	4.43
Expected dividend yield	0.00%	0.0%
Risk-free interest rate	0.41%	0.75%
Fair value per share	$16.83	$19.07

Series B redeemable convertible preferred stock warrants

	December 31, 2020	June 30, 2021
Expected volatility	46.2%	41.2%
Expected term (years)	7.91	7.41
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.65%	1.21%
Fair value per share	$16.41	$18.99

NOTE 13. STOCK-BASED COMPENSATION

Stock Incentive Plans

In August 2014, the Company adopted the 2014 Equity Incentive Plan ("2014 Plan") under which employees, non-employee directors and consultants of the Company may be granted either incentive stock options or non-qualified stock options to purchase shares of the Company's common stock. In January 2021, the Company increased the number of shares of common stock available for issuance under the 2014 Plan from 20,399,691 to 22,399,691.

As of December 31, 2020, and June 30, 2021, shares available for future grant under the 2014 Plan were 2,950,871 and 1,138,635, respectively.

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Stock-Based Compensation

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the six months ended June 30, 2020 and 2021, was as follows:

	Six Months Ended June 30,	
	2020	2021
Cost of revenue	$—	$ 343
Sales and marketing	—	26
Research and development	13	1,444
General and administrative	84	3,778
Total stock-based compensation expense	$97	$5,591

During the six months ended June 30, 2021, $0.1 million of stock-based compensation expense was capitalized to inventory during the manufacturing process.

Stock Options

A summary of stock option activity and related information for six months ended June 30, 2021 was as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at January 1, 2021	8,344,752	$ 0.61	6.44
Granted	2,975,821	15.56	
Exercised	(1,048,706)	0.26	
Forfeited	(219,878)	9.47	
Expired	(107,792)	0.37	
Outstanding at June 30, 2021	9,944,197	$ 4.93	7.26
Exercisable at June 30, 2021	5,568,512	$ 0.69	5.62
Vested and expected to vest at June 30, 2021	9,507,169	$ 4.68	7.16

The estimated fair value of each stock option award granted to employees was determined on the date of grant using the BSM option pricing model with the following assumptions for stock option grants for six months ended June 30, 2020 and 2021:

	2020	2021
Expected volatility	39.6%	40.9%
Expected term (years)	7.04	7.71
Expected dividend yield	0.0%	0.0%
Risk-free interest rate	0.41%	0.83%
Grant date fair value	$0.57	$6.93

As of June 30, 2020, there was $0.8 million of unamortized compensation cost related to unvested stock option awards. As of June 30, 2021, there was $14.0 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 3.41 years, on a straight-line basis.

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Restricted Stock Units

In February and March 2021, the Company issued a total of 1,049,043 restricted stock units (RSUs) with the right to receive common stock shares upon vesting schedule per agreements with its Chief Financial Officer and General Counsel. Vesting commenced on the first anniversary of the grant date over four years. Compensation expense is recognized over the requisite service period.

As of June 30, 2021, there was $12.0 million of unamortized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 3.69 years, on a straight-line basis.

Restricted Stock Purchase Agreements with Executives

In 2018 and 2020, the Company issued shares of common stock pursuant to Restricted Stock Purchase Agreements with its Chief Executive Officer and Chief Product Officer in exchange for Nonrecourse Notes totaling $1.4 million to finance 100% of the cost of the shares. Due to the Nonrecourse Notes being collateralized by the stock purchased and other stock held by the purchaser, these transactions are accounted for as substantive grants of common stock options since the employee does not assume the risk of ownership These shares are legally issued and outstanding and included on the balance sheet, but they are not treated as outstanding common stock for accounting purposes as they are deemed to be common stock options. Principal and interest payments received are recorded as a deposit liability until the Nonrecourse Notes are repaid at which time the deposit liability is transferred to additional paid-in capital.

A summary of the Company's option activity related to common stock through Nonrecourse Notes for the six months ended June 30, 2021 was as follows:

	Number of shares
Outstanding, December 31, 2020	9,872,293
Granted	—
Outstanding, June 30, 2021	9,872,293
Vested at June 30, 2021	8,044,384

The Company recognized the vesting of 360,516 shares of common stock subject to the 2018 restricted stock purchase agreements and 921,646 shares of common stock subject to the 2020 restricted stock purchase agreements that resulted in additional compensation expense $0.5 million for six months ended June 30, 2021. Total unrecognized compensation expense as of June 30, 2021 was $1.1 million.

Early Exercise Liability

The unvested shares of the early-exercised options are held in escrow until the stock option becomes fully vested or until the employee's termination, whichever occurs first. The right to repurchase these shares lapses over the four-year vesting period. As of June 30, 2021, the early exercise liability was approximately $0.1 million and is included in accrued liabilities in the balance sheets. There were no early exercised options prior to 2020. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest.

The following table summarizes the activity of the unvested common stock issued pursuant to an early exercise of stock option awards during the six months ended June 30, 2021:

	Number of Shares
Unvested at January 1, 2021	316,666
Early exercised stock options during period	—
Vested or cancelled	(189,998)
Unvested at June 30, 2021	126,668

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NOTE 14. INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average common shares outstanding during the period. Diluted net income (loss) per share attributable to common stockholders is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method and the if-converted method. Dilutive potential common shares include stock options, non-vested shares, redeemable convertible preferred shares, restricted stock and similar equity instruments granted by the Company. Potential common shares issuable in connection with the Company's Convertible Notes are accounted for under the contingent share method and were excluded from diluted income (loss) per share since they are only exercisable upon a contingent event that did not occur as of June 30, 2021. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

Basic and diluted net income (loss) attributable to common holders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock, common stock subject to restricted stock purchase agreements, early exercised options, and restricted shares are participating securities. Under the two-class method, distributed and undistributed income allocated to participating securities are excluded from net income (loss) attributable to common stockholders for purposes of calculating basic and diluted income (loss) per share. The Company's participating securities do not have a contractual obligation to share in the Company's losses, so the net loss for the six months ended June 30, 2020 was attributed entirely to common stockholders and there is no difference in the number of shares used to calculate basic and diluted shares outstanding. For the six months ended June 30, 2020, outstanding common stock for accounting purposes excludes 2,924,130 shares subject to restricted stock purchase agreements. For the six months ended June 30, 2021, outstanding common stock for accounting purposes excludes 9,872,293 shares subject to restricted stock purchase agreements and 126,668 unvested early exercised stock options.

The following table reconciles net income and the weighted-average shares used in computing basic and diluted earnings per share:

	Six Months Ended June 30,	
	2020	2021
Numerator:		
Net income (loss)	$ (19,278)	$ 32,840
Minus: Income allocated to participating securities	—	28,565
Net income (loss) attributable to common stockholders – basic	$ (19,278)	$ 4,275
Plus: Income allocated to non-participating securities	—	1,332
Net income (loss) attributable to common stockholders - diluted	$ (19,278)	$ 5,607
Denominator:		
Basic weighted-average common shares outstanding	15,909,439	18,617,247
Dilutive potential common stock issuable:		
Common stock warrants	—	89,551
Preferred stock warrants	—	74,149
Stock options	—	7,255,390
Diluted weighted-average shares outstanding	15,909,439	26,036,337
Net income (loss) attributable to common stockholders per share		
Basic	$ (1.21)	$ 0.23
Diluted	$ (1.21)	$ 0.22

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In periods of net losses, potentially dilutive securities are not included in the calculation of diluted net income (loss) per share because to do so would be anti-dilutive.

Outstanding anti-dilutive securities not included in the diluted net income (loss) per share attributable to common stockholders were as follows (in common stock equivalent shares):

	Six Months Ended June 30,	
	2020	2021
Redeemable convertible preferred stock	54,527,458	—
Stock options	8,244,751	1,789,378
Restricted stock units	—	1,049,043
Common stock subject to restricted stock purchase agreements	2,924,130	—
Common stock warrants	75,744	—
Redeemable convertible preferred stock warrants	79,882	—
Total	65,851,965	2,838,421

Potential shares issuable related to the Convertible Notes are excluded in the table above since the number of shares that will be issuable is dependent on a future event.

NOTE 15. INCOME TAXES

The Company's effective income tax rate for the six months ended June 30, 2021 was 29% compared to 0% in the corresponding period in the prior year. Income taxes for the six months ended June 30, 2021 include state income taxes in jurisdictions for which the Company does not have available tax attributes. The Company remains under a full valuation allowance with the exception of deferred tax liabilities arising for accelerated depreciation deductions for United States federal tax purposes. The effective tax rate for the six months ended June 30, 2020 differed from the statutory tax rate primarily due to the Company maintaining a full valuation allowance against its loss from operations for tax purposes.

The Company recorded a valuation allowance against all of its United States federal and state deferred tax assets as of December 31, 2020. At each interim period, the Company evaluates both the positive and negative evidence, which includes, projected future taxable income, scheduled reversals of deferred tax liabilities, prudent tax planning strategies, and recent financial operations, as to whether changes to the valuation assessment are needed.

As of June 30, 2021, the Company recorded $0.6 million of deferred tax liability to reflect the expected reversal of deferred tax liabilities in excess of deferred tax assets in certain future tax years. The Company continues to maintain a full valuation allowance on the remaining net deferred tax asset until there is sufficient evidence to support the reversal of all or an additional portion of the allowance.

On March 11, 2021, the American Rescue Plan Act H.R. 1319 (ARPA) was enacted and signed into law in the United States. ARPA is a follow up to the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The bill includes provisions on taxes, health care, unemployment benefits, direct payments, state and local funding, and other issues. ARPA did not have a significant impact on the Company's financial statements for the six months ended June 30, 2021.

In April 2021, the Company was awarded a California Competes Tax Credit (CCTC) totaling $20.0 million for a five-year agreement. The CCTC is a competitive income tax credit available to businesses across various industries that want to locate or expand in California. The CCTC can offset California corporate income tax liability and is non-refundable.

The credit is allocated in equal increments of $4.0 million over five years covering tax years 2021-2025, for a total of $20.0 million as documented in the CCTC Agreement. The credit is earned on an annual basis and certain milestones are required to be achieved. If the credit earned in a given year exceeds the Company's California

corporate income tax liability, the balance can be carried over for up to six years if necessary, until exhausted. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the six months ended June 30, 2021.

NOTE 16. COMMITMENTS AND CONTINGENCIES

Product Liability

The Company's business exposes it to liability risks from its potential medical diagnostic products. Product liability claims could result in the payment of significant amounts of money and divert management's attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes it carries reasonably adequate insurance for product liability.

Standby Letters of Credit

As of December 31, 2020, the Company was party to certain letters of credit ("LOC"), primarily related to a LOC with Comerica Bank as collateral required by one of the Company's vendors. During the three months ended March 31, 2021, the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the LOCs were no longer required by the counterparties. One LOC, totaling $6.0 million, was re-issued under the Revolving Credit Agreement.

In May 2021, the Company repaid the debt outstanding under the Revolving Credit Agreement and terminated the agreement in June 2021. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, the Company kept in place its outstanding LOC in the amount of $6.0 million, which has been cash collateralized.

NOTE 17. SUBSEQUENT EVENTS

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence for certain estimates or to identify matters that may require additional disclosure. The Company has completed an evaluation of all subsequent events through September 1, 2021, the date on which the financial statements were issued, and has further evaluated subsequent events through September 15, 2021, during which time nothing has occurred outside the normal course of business operations other than the events disclosed below.

Standby Letter of Credit

In July 2021, the Company increased its cash-collateralized outstanding letter of credit from $6.0 million to $12.0 million.

Forgiveness of Promissory Notes

In September 2021, the Company's board of directors canceled and forgave $8.3 million in principal and accrued interest under promissory notes between the Company and its Chief Executive Officer, comprised of $1.3 million under the promissory note issued in September 2018 and $7.0 million under the promissory note issued in July 2020. This action of the board of directors released 4,888,260 shares of common stock that had been pledged as collateral in connection with the September 2018 promissory note and 4,915,442 shares of common stock pledged as collateral in connection with the September 2020 promissory note.

In September 2021, the Company's board of directors canceled and forgave $3.5 million in principal and accrued interest under a promissory note issued in July 2020 between the Company and its Chief Product Officer and released 2,457,721 shares of common stock that had been pledged as collateral in connection with the promissory note.

The incremental compensation expense to be recognized by the Company is expected to be in line with the principal and interest balances being forgiven.

U.S. DoD Contract Amendment

In September 2021, the U.S. DoD Contract was amended to extend delivery of the 6,000,000 Cue Test Kits and other deliverables to December 31, 2021.

Authorized Stock Increase

In September 2021, the Company's board of directors and stockholders approved an increase to the number of authorized shares of the Company's common stock from 129,030,355 shares to 500,000,000 shares, which became effective on September 15, 2021.

2021 Equity Incentive Plans

In September 2021 the Company's board of directors adopted and the Company's stockholders approved the 2021 Equity Incentive Plan (the "2021 Plan"), which will become effective immediately prior to the effectiveness of the registration statement for this offering. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. Upon effectiveness of the 2021 Plan, the number of shares of our common stock that will be reserved for issuance under the 2021 Plan will be the sum of: (1) 14,173,771 shares; plus (2) the number of shares (up to a maximum of 22,399,691) as is equal to the sum of (x) the number of shares of our common stock reserved for issuance under the 2014 Plan that remain available for grant under the 2014 Plan immediately prior to the effectiveness of the registration statement of which this prospectus forms a part and (y) the number of shares of our common stock subject to outstanding awards under the 2014 Plan that expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, commencing on January 1, 2022 and continuing for each fiscal year until, and including, January 1, 2031, equal to the lesser of (i) 5% of the number of shares of our common stock outstanding on the first day of such fiscal year and (ii) the number of shares of our common stock determined by our board of directors.

In September 2021, the Company's board of directors adopted and the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which will become effective immediately prior to the effectiveness of the registration statement for this offering. The 2021 ESPP will be administered by the Company's board of directors or by a committee appointed by our board of directors. The 2021 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 2,834,754 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2021 ESPP will automatically increase on the first day of each fiscal year, commencing on January 1, 2022 and continuing until, and including, January 1, 2032, in an amount equal to the lowest of (i) 8,504,263 shares of our common stock, (ii) 1% of the number of shares of our common stock outstanding on such date and (iii) a number of shares of our common stock determined by our board of directors.

We seek to usher in a new era in healthcare.

* Depicts certain of our future planned care offerings which are subject to completion of development and may require regulatory authorization, clearance, or approval before they can be commercialized. Currently, our COVID-19 Test Kit is our first and only commercially available Test Kit, which has been authorized under two FDA EUAs for point-of-care and over-the-counter at-home use. Our COVID-19 test has also received regulatory approval from the Central Drugs Standard Control Organisation, India's national regulatory body for pharmaceuticals and medical devices, for professional point-of-care use in India, the CE mark in the European Union and Interim Order authorization from Health Canada.

12,500,000 Shares

Common Stock

Prospectus

Joint Book-Running Managers

Goldman Sachs & Co. LLC **Morgan Stanley** **Cowen**

Lead Manager

BTIG

September 23, 2021