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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For transition period from to

Commission File Number 001-40590

Cue Health Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-1562193**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

4980 Carroll Canyon Rd., Suite 100
San Diego, CA 92121
(858) 412-8151

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.00001 par value	HLTH	Nasdaq Global Select Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

As of June 30, 2021, the last business day of the registrant’s most recently completed second fiscal quarter, there was no established public market for the registrant’s common stock and, therefore, the registrant cannot calculate the aggregate market value of its common stock held by non-affiliates as of such date. The aggregate market value of the common stock held by non-affiliates of the registrant as of December 31, 2021 (the last business day of the registrant’s most recently completed fourth fiscal quarter) was approximately $885 million based on the closing price of the registrant’s common stock on December 31, 2021 of $13.41 per share, as reported by the Nasdaq Global Select Market (“Nasdaq”). Shares of the registrant’s common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 21, 2022, there were approximately 146,629,118 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required to be included in Part III of this Annual Report on Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of these words, variations of these words or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. Such forward-looking statements are subject to certain risks, uncertainties and assumptions relating to factors that could cause actual results to differ materially from those anticipated in such statements, including, without limitation, the following:

- our expectations regarding our revenue, expenses and other operating results;
- the extent and duration of the Corona Virus Disease ("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 agreements with 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 (Emergency Use Authorization) 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;
- 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; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, results of operations, financial condition, and prospects.

The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Item 1.A "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We cannot assure you that the results, events, and circumstances reflected in the

forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this report or to reflect new information or the occurrence of unanticipated events, except as required by law. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Part I

Item 1. Business

BUSINESS

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. 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 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 Cue 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, an Interim Order authorization from Health Canada, and authorization in Singapore from the Health Sciences Authority, are examples of this. Users can run a COVID-19 test anywhere using the Cue Reader and a Cue COVID-19 Test Kit, and have lab-quality test results delivered digitally to the user's mobile device in about 20 minutes. While our Cue 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 Cue 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.

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. 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.

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 Cue 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.

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 our Cue COVID-19 Test Kits, subject to limited exceptions. The U.S. DoD agreement initially contemplated a ramp-up in our production to 100,000 Cue 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 our Cue COVID-19 Test Kits to additional customers. Notwithstanding the waiver granted to us by the U.S. DoD, we were 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. We have fulfilled the requirement 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. 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 Cue 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. Our current manufacturing capacity is at a rate of over 20 million Cue Cartridges per year.

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 $618.1 million of revenue for the year ended December 31, 2021, of which approximately $615.8 million was from product sales. Of this amount, $383.0 million of total revenue was from public sector entities, substantially all of which was from the U.S. DoD, and the remaining $232.8 million of total revenue was generated from other customers. In 2020, we generated $23.0 million of total revenue, of which $8.9 million was from public sector entities. The U.S. DoD and Henry Schein accounted for approximately 53.1% of our total revenue in 2020. In 2019, we generated $6.6 million of total revenue, none of which was from product sales. With the conclusion of the initial U.S. DoD contract in December 2021, we anticipate that the related increased end-market flexibility along with improved sales and distribution capabilities will increase the percentage of our revenue derived from non-public sector customers. For the year ended December 31, 2021, our net income was $86.4 million. In 2020, we incurred a net loss of $47.4 million.

Our Solution

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 users to have reliable information at their fingertips to make faster and more informed healthcare decisions. The Cue Integrated Care Platform consists of the following hardware and software components.

Cue Health Monitoring System

The Cue Health Monitoring System consists of our Cue Reader and Cue Test Kit. 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 is designed to be universally compatible with our current and planned future Cue Cartridges. Each Cue Test Kit is comprised of a Cue Cartridge and a Cue Wand. The Cue Cartridge is a sample-specific, single-use cartridge designed to handle different chemistries. Each Cue Cartridge contains the

specific reagents and associated materials required to detect the target of the particular test and is designed with ease-of-use, user safety, and scalability in mind. The Cue Wand is a single-use and sterile sample collection device designed to permit collection of multiple sample types, including saliva, blood, urine, and swab, with only minor modification. When a Cue Wand is inserted into the associated Cue Cartridge the system automatically runs the test and delivers the result to our Cue Health App.

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 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

Our Cue Virtual Care Delivery Apps consist of the Cue Health App and the Cue Enterprise Dashboard. To run a Test Kit on the Cue Reader, a user will need to download and utilize the Cue Health App. This 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. The Cue Enterprise 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 efficiency 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. 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 decision making.

Cue Ecosystem Integrations and Apps

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.

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 nucleic acid amplification tests ("NAAT") or immunoassay to perform a test. In both cases, an internal or process control confirms proper assay execution including, as relevant, sample analysis, amplification, sample flow and assay reagent function. Once the assay begins, all heating, mixing, amplification and detection takes place within the Cue Cartridge with no steps by the user. The Cue Reader then communicates the test result digitally, directly and wirelessly to the Cue Virtual Care Delivery Apps.

Our Testing Technologies

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 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 natively digital 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 160,000 Cue Readers across the United States as of December 31, 2021, including Cue Readers placed through our U.S. DoD Agreement 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.

Strategic Collaborations and Certain Other Agreements

U.S. Government

- BARDA - We have partnered with the U.S. Biomedical Advanced Research and Development Authority, or 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 2023. 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. Furthermore, in January 2022, the scope of our partnership with BARDA was increased to include our development of an Omicron-Genotyping COVID-19 test to be used in professional point-of-care settings.

- 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. In December 2021, we completed the shipment of all required Cue Readers, Control Swab Packs and 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, the U.S. HHS is using our COVID-19 test to verify the results of antigen tests, 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. As of December 31, 2021, we have delivered 6 million of our COVID-19 tests under the pilot program.
  - 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 allowed 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 also agreed to provide regular reports as to the status of our production and distribution.
  - 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 2021. In November 2021, this agreement was

renewed through June 30, 2022. Under the renewed agreement, Google's U.S.-based employees were given access to proctoring services.

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 Cue 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 Cue 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.

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 approval 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 160,000 Cue Readers as of December 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 recently rolled out our direct-to-consumer offering, providing retail customers the ability to purchase Cue products directly through our app and website. 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 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 completed 13 new production pods. Our current manufacturing capacity is at a rate of over 20 million Cue Cartridges per year.
- ***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. In November 2021, we received authorization in Singapore from the Health Sciences Authority (HSA) for the Cue COVID-19 Test under the Pandemic Special Access Route (PSAR).

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 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 Cue COVID-19 Test Kit are authorized pursuant to our EUA authorizations, to date we have not obtained a 510(k) clearance for our Cue 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. The 510(k) studies have commenced.

We have an agreement with BARDA which covers the development, EUA and 510(k) clearance of our COVID- 19 Test Kit. There is approximately $5.0 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 Clinical Research Organization, or 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 completed

clinical enrollment in February 2022, ahead of schedule, and expect to submit our COVID-19 Test Kit to the FDA for de novo review in the second quarter of 2022 for 510(k) clearance.

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 Cue COVID-19 Test Kits, has significantly accelerated our installed base growth, which we believe will enable continued distribution of our Cue 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 the U.S. DoD agreement, the Cue Health Monitoring System and Cue COVID-19 Test Kits have been deployed to at least 18 states, thousands of schools, nursing homes, hospitals, essential businesses, correctional facilities, underserved communities, public health facilities and organizations as well as other public sector users, as of December 31, 2021.

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 future opportunities for 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 Cue 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.

Research and Development

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.

Our research and development strategy continues to focus 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.

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.

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 December 31, 2021, we owned twenty-two (22) 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-five (25) 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 2038, 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 December 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.

We also rely upon trademarks to build and maintain the integrity of our brand. As of December 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 publicly 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.

Manufacturing and Suppliers

Our products are manufactured within our facilities in San Diego and at other third party locations. Our products contain some components and raw materials that we purchase globally from single-source direct and indirect suppliers, some without long-term supply agreements, such as electronic components and certain chemical reagents. We do, however, periodically purchase quantities of some of these critical components in excess of current requirements, in anticipation of future manufacturing needs. See the applicable risk factor in Item 1.A. “Risk Factors” for an additional description of this risk.

Employees and Human Capital Resources

As of December 31, 2021, we had 1,585 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 December 31, 2021, the Vista facility was producing cartridges from seven production pods (with space for an additional three production pods) and is serving as our warehousing and distribution hub. Our Waples facility serves as a second reagent production hub, houses 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

The development, testing, manufacturing, marketing, post-market surveillance, distribution, advertising and labeling of medical devices are subject to regulation in the United States by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA) and comparable state agencies. Unless subject to an exemption, medical devices must receive from the FDA prior to marketing either clearance of a premarket notification, known as 510(k), or premarket approval (PMA) pursuant to the FDCA. The FDA classifies medical devices into one of three classes based upon their risk profile: Class I devices are relatively simple “low risk” technologies that can be manufactured and distributed with general controls without a premarket clearance or approval from the FDA; Class II devices are somewhat more complex “moderate risk” devices that require greater scrutiny from the FDA and require premarket clearance from the FDA before market entry; and Class III devices are “high risk” technologies inserted or implanted in the body, intended to treat life sustaining functions. Class III technologies require premarket approval from the FDA before market entry. If we are required to submit our products for pre-market review by the FDA, we may be required to delay marketing and commercialization while we obtain premarket clearance or approval from the FDA. There would be no assurance that we could ever obtain such clearance or approval.

All medical devices that are regulated by the FDA are also subject to the quality system regulation. Obtaining the requisite regulatory approvals, including the FDA quality system inspections that are required for PMA approval, can be expensive and may involve considerable delay. The regulatory approval process for such products may be delayed, may be more expensive than anticipated, and may conclude without such products being approved by the FDA. Without timely regulatory approval, we will not be able to launch or successfully commercialize such diagnostic products. Changes to the current regulatory framework, including the imposition of additional or new regulations, could arise at any time during the development or marketing of our products. This may negatively affect our ability to obtain or maintain FDA or comparable regulatory clearance or approval of our products in the future. In addition, the FDA may introduce new requirements that may change the regulatory requirements for us or our customers, or both.

Emergency Use Authorization

In emergency situations, such as a pandemic, the FDA has the authority to authorize 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 Emergency Use Authorization (“EUA”) for an unapproved device if certain statutory criteria are met. Once granted, an EUA will remain in effect and generally terminate on the earlier of a determination that the public health emergency has ceased or a change in the approval status of the product. 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 February 4, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19. We received an EUA from the FDA on June 10, 2020 (designated as EUA 200248) 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 and to update the test protocol and Quick Reference Index to include instructions for the new specimen type. On March 26, 2021, in response to Cue Health's request, the FDA re-issued our June 10, 2020 EUA No. 200248 to include the previously authorized indication and intended use along with the August 20, 2020 amendments, and revised the EUA to update the indication, intended use, and conditions of authorization. We received a second EUA from the FDA on March 5, 2021 (designated as EUA Number 210180) 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. Both EUAs are subject to certain Conditions of Authorization as listed in each EUA letter, including but not limited to conditions related to advertising, printed materials, and promotion.

510(k) Clearance Marketing Pathway

We expect that many of our future tests will require clearance under 510(k) regulatory pathway, unless exempted or otherwise authorized pursuant to an EUA. Our current products are Class II medical devices and, but for the immediate ability to seek an EUA, would be subject to premarket notification and clearance requirements 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, the FDA has 90 calendar days by regulation 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 $12,745.

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.

PMA Approval Pathway

None of our tests are currently approved under 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 could require the approval of PMA. Class III devices require PMA approval before they can be marketed in the U.S. The PMA process is generally more

demanding than the 510(k) process. A PMA must be supported by extensive data, including data from pre-clinical studies and clinical trials demonstrating that the device is safe and effective. 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.

De Novo Classification

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 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. 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. 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.

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.

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 requirements; Quality System Regulation (QSR) requirements; labeling and advertising regulations; product modification requirements; medical device reporting regulations; product correction, and recall regulations; and post-market surveillance activities.

Advertising and promotion of medical devices 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.

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 number of sanctions including warning letters, fines, injunctions, production suspension, and/or civil and criminal penalties.

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 categorization 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 HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the transmission, security and privacy of protected health information by covered entities subject to HIPAA, such as health plans, health care clearinghouses and healthcare providers, and their respective business associates that access protected health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new 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.

In addition, in the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, in June 2018, the State of California enacted the CCPA, which came into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies. 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.

While we are not currently subject to the CCPA or the CPRA, we may in the future be required to comply with the CCPA or the CPRA, which may increase our compliance costs and potential liability. Furthermore, the CCPA and CPRA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Other International Privacy and Security Regulations

The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area (EEA), including personal health data, is subject to the General Data Protection Regulation (Regulation (EU) 2016/679), or the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. As of January 1, 2021, and the expiry of transitional arrangements agreed to between the United Kingdom and EU, data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), exposing us to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for certain violations. There will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and EEA.

U.S. Federal, State and Foreign Fraud and Abuse Laws

U.S. Federal and State Fraud and Abuse Laws

A variety of state and federal laws prohibit fraud and abuse involving state and federal health care programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for the Department of Health and Human Services, the OIG, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. Any overpayments must be repaid within 60 days of identification unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger set of claims, and which can result in even higher repayments.. Our business is subject to compliance with these laws.

Anti-Kickback Statutes. The Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. "Remuneration" is broadly defined to include anything of monetary value, such as, for example, cash payments, gifts or gift certificates, discounts, or the furnishing of services, supplies or equipment. The Anti-Kickback Statute can be interpreted broadly to prohibit many arrangements and practices that are lawful in businesses outside of the health care industry. Recognizing the potential breadth of interpretation of the Anti-Kickback Statute and the fact that it may technically prohibit many otherwise innocuous or beneficial arrangements within the health care industry, the OIG has issued a series of regulations, or safe harbors intended to protect such arrangements. Compliance with all requirements of a safe harbor immunizes the parties to the business arrangement from prosecution under the Anti-Kickback Statute. The failure of a business arrangement to fit within a safe harbor does not necessarily mean that the arrangement is illegal or that the OIG will pursue prosecution but would be evaluated on a case-by-case basis. Still, in the absence of an applicable safe harbor, a violation of the Anti-Kickback Statute may occur even if only one purpose of an arrangement is to induce referrals. The penalties for violating the Anti-Kickback Statute can be severe. These sanctions include criminal, civil and administrative penalties, imprisonment and possible exclusion from the federal health care programs. Many states have adopted laws similar to the Anti-

Kickback Statute, and some apply to items and services reimbursable by any payor, including private third-party payors. Further, the 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). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal Anti-Kickback Statute exceptions and safe harbors, and others that materially differ.

State and Federal False Claims Laws. The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. Under the False Claims Act, a person acts knowingly if he or she has actual knowledge of the information or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the information. Specific intent to defraud is not required. The qui tam provisions of the False Claims Act allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. Penalties include payment of up to three times the actual damages sustained by the government, plus significant civil penalties, as well as possible exclusion from federal health care programs. In addition, various states have enacted similar laws modeled after the False Claims Act that apply to items and services reimbursed under Medicaid and other state health care programs, and, in several states, such laws apply to claims submitted to any payor.

Physician Self-Referral Bans. The federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare patients to an entity providing certain designated health services, which include laboratory services, if the physician or an immediate family member of the physician has any financial relationship with the entity. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including but not limited to: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements; and (4) personal services arrangements. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from federal health care programs. In addition to the Stark Law, many states have their own self-referral bans, which may extend to all self-referrals, regardless of the payor.

Civil Monetary Penalties Law. The federal Civil Monetary Penalties Law, or the CMP Law, prohibits, among other things, (1) the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies; (2) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal health care program; (3) billing for services requested by an unlicensed physician or an excluded provider; and (4) billing for medically unnecessary services. The penalties for violating the CMP Law include exclusion, substantial fines, and payment of up to three times the amount billed, depending on the nature of the offense.

Transparency Laws and Regulations. 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.

International 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. We are also required to maintain accurate information on and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act, its books and records provisions and its anti-bribery provisions.

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.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes, before making a decision to invest in our common stock. Our business, results of operations, financial condition or prospects could also be harmed by risks and uncertainties that are not presently known to us or that we currently believe are not material. If any of the risks actually occur, our business, results of operations and financial condition could be adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment.

Summary Risk Factors

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition, results of operations and prospects could be materially harmed and the market price of our common stock could significantly decline:

- 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 Cue 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 have historically relied upon the U.S. DoD and a 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.

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 Cue 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 year ended December 31, 2021, we had a net income of $86.4 million. As of December 31, 2021, we had an accumulated deficit of $24.0 million. While we were profitable for the first time in 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. 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 Cue 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 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, our ability to expand our customer relationships 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 Cue 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 Cue 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 Cue 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.

We also received authorization in Singapore from the Health Sciences Authority (HSA) for the Cue COVID-19 Test under the Pandemic Special Access Route (PSAR). If the authorization is revoked or terminated, we would lose our ability to expand into the Singaporean 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 Cue COVID-19 Test Kit. If our Cue 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 Cue COVID-19 Test Kit, which currently is our only commercially available test. The continued commercial success of our Cue 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 Cue 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 test offerings.

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 Cue 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 Cue 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;
- 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 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 Cue 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 have historically relied upon the U.S. DoD and a small number of other customers for almost all of our current total 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, 2021 and 2020, the U.S. DoD accounted for approximately 61.4% and 38.7% of our total revenue, respectively. A single non-government enterprise customer accounted for approximately 24.4% of our total revenue during the year ended December 31, 2021. We have fulfilled our obligations and received our final payment under the initial DoD Agreement. As a result, we anticipate that our public sector revenue will decline significantly and that we will be largely dependent on new and existing private sector customers for our revenue. Should we enter into a follow-on Federal Acquisition Regulation, or FAR-based, contract, 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. We have not yet commenced negotiations for a FAR-based contract and there is no guarantee that the U.S. DoD will enter into a FAR-based contract or any other agreements. Any such additional contract with the U.S. DoD could constrain our ability to grow our business with non-U.S. government customers. 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 our other major customers, or a significant reduction in the amount of our products purchased by our 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.

If the U.S. DoD fails to enter into a new agreement, our business, results of operations, financial condition and future prospects may be materially adversely affected.

The U.S. DoD Agreement required us to 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 the U.S. DoD Agreement, we were 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 Cue 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 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 our Cue COVID-19 Test Kits was approximately 2,000 cartridges per day. By December 31, 2021, we had fulfilled the requirement to ramp up our production capacity to approximately 100,000 Cue COVID-19 Test Kits per day for a seven-day period. Additionally, we complied with our obligation to deliver all of the Cue Readers as required under the U.S. DoD Agreement. Even though we have satisfied our obligations under the U.S. DoD Agreement, it is possible that we may not be able to enter into a new agreement with the U.S. DoD for these or other care offerings, and thus our business, results of operations, financial condition and future prospects may be materially adversely affected.

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

From January 1, 2020 to December 31, 2021, the number of our employees increased from 99 to 1,585 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 total 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 Care 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 report 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 were a private company from our inception until the closing of our IPO on September 28, 2021, and, as such, we previously had 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 next fiscal year. As a result of becoming a public company, we are 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 2021, 2020, and 2019 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, experience and training important to our financial reporting requirements, and the review of journal entries, and in 2020 and 2019, insufficient complement of qualified resources with an appropriate level of knowledge and timely reconciliation and analysis of certain key accounts. 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 our IPO, 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 and a Chief Financial Officer in the first quarter of 2021, the hiring of a Vice President and Treasurer in the second quarter of 2021, and beginning in the fourth quarter of 2021 we added an Interim Controller, Assistant Controller and a Director of Tax, and the continued engagement of additional external advisors to provide financial accounting assistance in the short term. We have substantially grown our team 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. As part of our ongoing efforts to remediate our material weaknesses during fiscal 2021, management began capturing and documenting current state processes while identifying opportunities for process improvement in preparation for and in conjunction with the Company's implementation of Sarbanes-Oxley. In addition, we continue to engage 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 have evaluated 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 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 "Item 3. 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. Also, due to political uncertainty and military actions associated with Russia's invasion of Ukraine, we and our third-party vendors and service providers are vulnerable to a heightened risk of cybersecurity attacks, phishing attacks, viruses, malware, ransomware, hacking or similar breaches from nation-state actors, including attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products and services. 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, some of our employees continue to work 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. In November 2021, we received authorization in Singapore from the Health Sciences Authority (HSA) for the Cue COVID-19 Test under the Pandemic Special Access Route (PSAR). 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;
- political and economic instability related to the military conflict between Russian and Ukraine and the related impact on macroeconomic conditions as a result of such conflict, which may negatively impact our customers and distributors;
- 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. Furthermore, U.S. export control laws and economic sanctions in many cases prohibit the export of software and services to certain U.S. embargoed or sanctioned countries, governments and persons, as well as for prohibited end-uses. For example, following Russia's invasion of Ukraine, the United States and other countries imposed economic sanctions and severe export control restrictions against Russia and Belarus, and the United States and other countries could impose wider sanctions and export restrictions and take other actions should the conflict further escalate. 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 report.

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 report.

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. On March 11, 2021, the American Rescue Plan Act H.R. 1319 (ARPA) was enacted and signed into law in the United States. 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.

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.

Regulatory guidance under the TCJA, the FFCR Act, the CARES Act, the CAA, the ARPA, and California AB 85 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, the CAA, or the ARPA.

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, 2021, we had federal and state NOL carryforwards of approximately $9.7 million and $60.6 million, respectively. The federal NOL carryforwards generated in pre-2018 tax years of $5.6 million will begin to expire in 2037 while Federal NOLs generated after 2017 of $4.1 million will carryforward indefinitely. The state NOL carryforwards of $60.6 million will begin to expire in 2031 unless previously utilized. At December 31, 2021, the Company also had federal research tax credit carryforwards of $1.2 million. The federal research tax credit carryforwards begin to expire in 2032, if not utilized.

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, 2021, 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 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. 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 periods 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 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 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 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.

Because we sell our products internationally, we are faced with increasingly complex tax issues in many jurisdictions, and we could be obligated to pay additional taxes in various jurisdictions.

Because we sell our products internationally, 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 could 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.

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, acts of terrorism, acts of war, including Russian's invasion of Ukraine, other geopolitical unrest, 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 some components and raw materials that we purchase globally from single-source direct and indirect suppliers, some 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. 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 Quality System Regulation'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.

For example, in the past, we have received inquiries from the FDA into the marketing of our tests, reporting of any potential inaccurate test results, and canceled tests. 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 adopted a code of business conduct and ethics 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

An active trading market for our common stock may not be sustained.

An active public trading market for our common stock 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.

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;
- 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, including as a result of military conflict between Russia and Ukraine; 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. 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.

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 report, 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.

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.

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 December 31, 2021, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in the aggregate, beneficially own approximately 54.9% of our common stock. 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.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws 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, 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 acquirers 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.

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 are 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 our IPO. 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 2020 and 2021 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 designates 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 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 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease real property to support our business, including manufacturing, research and development, sales, marketing and administration. The following lists those properties that we believe are material to our business as of December 31, 2021:

Location	Status	Lease Term	Square Footage	Primary Use
Vista, CA (Vista)	Leased	2031 - two options to extend for a term of 5 years each	197,000	Manufacturing
San Diego, CA (Waples)	Leased	2031 - two options to extend for a term of 5 years each	64,000	Manufacturing and research and development
San Diego, CA (Nancy Ridge)	Leased	2027 - one option to extend for a term of 5 years	28,000	Administrative offices, manufacturing and research and development
San Diego, CA (Carroll Canyon)	Leased	2030 - one option to extend for a term of 5 years	21,000	Headquarters, administrative offices, manufacturing, and research and development

We believe that our facilities are adequate for our current needs, and we currently do not anticipate any material difficulty in renewing any of our leases as they expire or securing additional or replacement facilities, in each case, on commercially reasonable terms. However, in anticipation of our growth strategy, we may pursue additional facilities.

Item 3. 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.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock began trading on the Nasdaq under the ticker symbol “HLTH” on September 24, 2021. Prior to that time, there was no public market for our common stock.

Holders

As of February 28, 2022, there were 199 holders of our common stock. This figure does not include a substantially greater number of “street name” holders or beneficial holders of our common stock whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

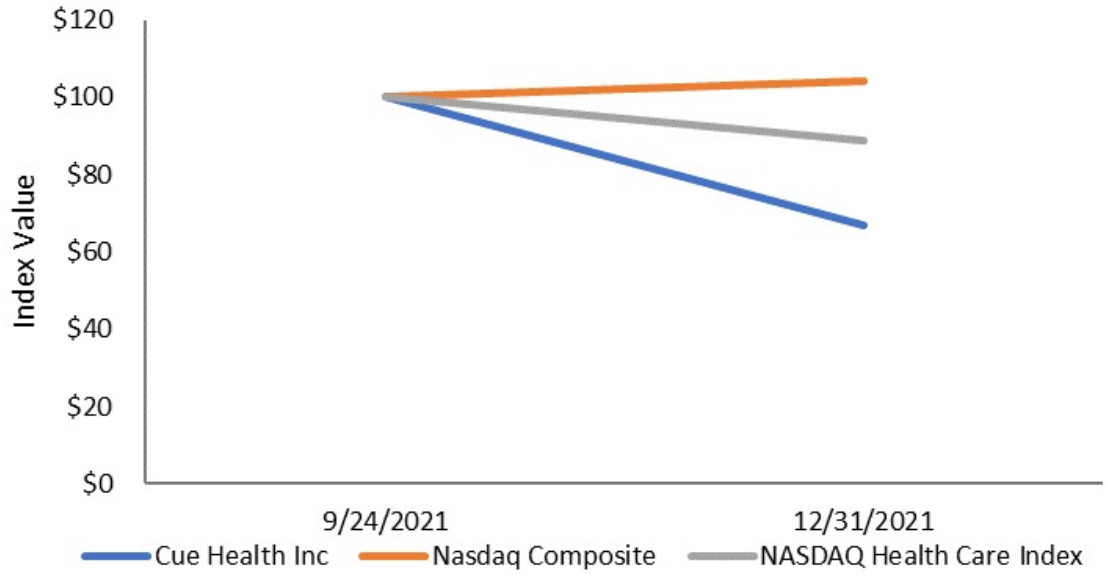
Securities Authorized for Issuance under Equity Compensation Plans

For information regarding securities authorized for issuance under equity compensation plans, see Part III, Item 12 of this Annual Report on Form 10-K.

Stock Performance Graph

The following graph shows a comparison from September 24, 2021 (the date our common stock commenced trading on the Nasdaq) through December 31, 2021 of the cumulative total return for our common stock based on the closing price on the last day of each respective period, relative to the Nasdaq Composite Index (“Nasdaq Composite”) and the Nasdaq Medical Equipment Index (“Nasdaq Medical”). The graph assumes an initial investment of $100 on September 24, 2021 in the common stock of the Company, the Nasdaq Composite and Nasdaq Medical, and assumes reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

Cue Health Inc. Comparison of Cumulative Total Return Performance



Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

From January 1, 2020 through September 24, 2021 (the date of the filing of our registration statement on Form S-8), we granted our directors, officers, employees, consultants and other services providers restricted stock units for an aggregate of 1,177,043 shares of our common stock under our 2014 Plan and restricted stock awards for an aggregate of 7,373,163 shares of our common stock under our 2014 Plan.

From January 1, 2020 through September 24, 2021 (the date of the filing of our registration statement on Form S-8), we granted our directors, officers, employees, consultants and other services providers an aggregate of 5,198,863 shares of common stock upon the exercise of options issued under our 2014 Plan at a weighted-average exercise price of $9.51 per share, for an aggregate exercise price of $49,445,055.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales, and issuances of the above securities were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds

On September 28, 2021, we completed our IPO, in which we sold 14,375,000 shares of our common stock at an offering price of $16.00 per share, including 1,875,000 shares pursuant to the exercise in full of the underwriters' option to purchase additional shares. We received net proceeds of $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act of 1933, as amended pursuant to a registration statement on Form S-1 (File No. 333-259250), which was declared effective by the SEC on September 23, 2021. The representatives of the underwriters of our IPO were Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. As of December 31, 2021, approximately $24.0 million of expenses incurred in connection with our IPO had been paid.

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final prospectus.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You *should read the following discussion and analysis of our financial condition and results of operations together with the financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in or* implied *by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Annual Report on Form 10-K titled "Risk Factors." For a discussion related to the results of operations for 2020 compared to 2019, refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2021 S-1 filed with the Securities and Exchange Commission on September 23, 2021.*

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 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, 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.

Initial Public Offering

The Company's registration statement related to its initial public offering ("IPO") was declared effective on September 23, 2021, and the Company's common stock began trading on the Nasdaq Global Select Market ("Nasdaq") on September 24, 2021. On September 28, 2021, the Company completed its IPO of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased by the IPO underwriters. The Company received aggregate net proceeds of approximately $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

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 total revenue for our COVID-19 test in August 2020 after obtaining our first FDA EUA in June 2020. Currently, all of our revenue is related to sales of our Cue COVID-19 test.

In December 2020, the FDA issued EUA 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 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 having 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.

Certain Key Factors Affecting Our Performance

Manufacturing Capacity

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 continue to optimize our manufacturing capabilities, including our fully automated production pods. A production pod is a free standing, modular environmentally controlled structure containing an automated cartridge production line.

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

Following the completion of our obligations under the U.S. DoD Agreement, the future commercial success of our diagnostic products is dependent on our ability to broaden our customer base beyond the U.S. government and public sector to include enterprise employers, healthcare providers and direct-to-consumer. As a result, our long term growth depends on our ability to renew and acquire new customers. Current key strategic relationships include BARDA, Google LLC, or Google, the Mayo Clinic, the National Basketball Association, and Henry Schein, Inc. 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. For the year ended December 31, 2021, we sold over 155,000 readers and have sold over 160,000 readers since our first FDA EUA in June 2020.

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. 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. 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.

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 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 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. 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.

Year Ended 2021 Summary (on a comparative basis)

Key GAAP financial results for the year ended December 31, 2021 were as follows as compared to the year ended December 31, 2020:

- Revenues increased to $618.1 million from $23.0 million;
- Product gross margin was 55% compared to 3%;
- Net income increased to $86.4 million from $47.4 million net loss and;
- Earnings per diluted share increased to $0.59 from a $2.90 loss per diluted share.

Key non-GAAP financial results for the year ended December 31, 2021 were as follows as compared to the year ended December 31, 2020:

- Non-GAAP adjusted net income increased to $164.5 million from $47.4 net loss; and
- Non-GAAP adjusted earnings per diluted share increased to $1.21 from a $2.90 loss per diluted share.

Please see a description in the *Non-GAAP Financial Measures* section below.

Components of Our Results of Operations

Revenue

Our product revenue currently primarily relates to sales of our COVID-19 test, which began in August 2020 after we obtained our initial EUA in June 2020. With respect to the U.S. DoD Agreement, the transaction price was fixed and did

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 December 31, 2021 is $92.4 million. Of this amount, $82.2 million was classified as current as of December 31, 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 $92.4 million of contract value under the U.S. DoD Agreement, that had not been recognized by us as of December 31, 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. Commercial customers outside of the U.S. government accounted for approximately 37.7% of our total revenue for the year ended December 31, 2021.

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 2023. 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 $36.3 million in contracts and awards, $21.8 million for phase one and $14.5 million for phase two, from BARDA from June 2018 to December 31, 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 or 2021. The direct costs associated with both contracts are reflected as a component of research and development expense in our statements of operations. BARDA revenue recognized for the year ended December 31, 2021 was $2.2 million.

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. 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 our costs as a percentage of revenue to vary from period to period depending on the number of units produced to satisfy demand.

Sales and Marketing Expense. Our sales and marketing expense consists primarily of salaries, commissions, 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 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 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:

(dollars in thousands)	Year Ended December 31, 2021	2020	2019
External costs	$ 3,612	$ 4,441	$ 1,534
Internal costs			
Salaries and benefits	19,766	7,607	8,366
Facilities and supplies	19,451	16,430	11,505
Total internal costs	39,217	24,037	19,871
Total research and development costs	$ 42,829	$ 28,478	$ 21,405

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. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, we are keeping in place our outstanding letter of credit in the amount of $12.0 million, which will be cash collateralized. All other obligations under the Revolving Credit Agreement have otherwise been terminated. 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

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth a summary of our results of operations for the years ended December 31, 2021 and 2020, and the changes between periods:

	Year Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
(dollars in thousands)				
Revenue:				
Product revenue	$ 615,796	$ 15,391	$ 600,405	3,901%
Grant and other revenue	2,311	7,562	(5,251)	(69%)
Total revenue	618,107	22,953	595,154	2,593%
Operating costs and expenses:				
Cost of product revenue[(1)(2)]	276,542	14,951	261,591	1,750%
Sales and marketing[(1)]	28,729	714	28,015	3,924%
Research and development[(1)]	42,829	28,478	14,351	50%
General and administrative[(1)]	79,788	23,936	55,852	233%
Total operating costs and expenses	427,888	68,079	359,809	529%
Income (loss) from operations	190,219	(45,126)	235,345	(522%)
Interest expense	(9,809)	(374)	(9,435)	2,523%
Change in fair value of redeemable convertible preferred stock warrants	53	(1,289)	1,342	(104%)
Change in fair value of convertible notes	(59,560)	—	(59,560)	n.m
Loss on extinguishment of debt	(1,998)	(610)	(1,388)	228%
Other income (expense), net	272	47	225	479%
Net income (loss) before income taxes	119,177	(47,352)	166,529	(352%)
Income tax expense	32,759	—	32,759	n.m
Net income (loss)	$ 86,418	$ (47,352)	$ 133,770	(283%)
Net income (loss) per share attributable to common stockholders – diluted	$ 0.59	$ (2.90)	$ 3.49	(120%)

n.m. = not meaningful

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

	Year Ended December 31,	
	2021	**2020**
(dollars in thousands)		
Cost of product revenue	$ 1,979	$ —
Sales and marketing	2,634	1
Research and development	6,889	98
General and administrative	31,477	3,064
Total stock-based compensation expense	$ 42,979	$ 3,163

(2) Includes $27.9 million and $2.1 million of depreciation and amortization expense for the years ended December 31, 2021 and 2020, respectively.

Revenue increased to $618.1 million for the year ended December 31, 2021, from $23.0 million for the year ended December 31, 2020. The increase was primarily due to the commencement of product sales in August 2020 and continued expansion of our customer base. Revenue during the year ended December 31, 2021 was driven by sales to public sector clients, primarily from our U.S. DoD Agreement, where we recognized $383.0 million of revenue along with sales to private sector customers of $232.8 million.

Cost of *Product Revenue* increased to $276.5 million for the year ended December 31, 2021, from $15.0 million for the year ended December 31, 2020. This increase was primarily 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. Our product gross profit margin, or product gross profit as a percentage of product revenue was approximately 55% in the year ended December 31, 2021 compared to approximately 3%, in the year ended December 31, 2020. The increase in gross profit margin was driven by scaling up production and related efficiencies that resulted in more favorable absorption of fixed costs on a per unit basis in 2021.

Sales and Marketing Expense increased to $28.7 million for the year ended December 31, 2021 from $0.7 million for the year ended December 31, 2020. This increase was due to the launch of our COVID-19 test in August 2020 and increased sales and marketing personnel costs to support the expected growth and demand for our products, higher expenses related to digital marketing services and increased headcount to support the growth of our business.

Research and Development Expense increased to $42.8 million for the year ended December 31, 2021, from $28.5 million for the year ended December 31, 2020. This increase was primarily driven by higher research and development spend associated new product development and early costs related to upcoming clinical studies for 510(k) approval of our COVID-19 and influenza tests. Our research and development expenses primarily consist of engineering and research expenses related to our continuous COVID-19 and influenza technology, clinical trials, regulatory expenses, quality assurance programs, materials and products for clinical trials. We also incur significant expenses to operate our clinical trials including clinical site reimbursement, clinical trial product and associated travel expenses.

General and Administrative Expense increased to $79.8 million for the year ended December 31, 2021 from $23.9 million for the year ended December 31, 2020. This increase was primarily related to an increase in stock-based compensation expenses, legal, banking, headcount growth to build out central team, accounting and other consulting-related costs to support our growing business and prepare us to operate as a public company after our IPO in September 2021.

Interest Expense increased to $9.8 million for the year ended December 31, 2021 from $0.4 million for the year ended December 31, 2020. The increase was primarily driven by $6.0 million of issuance costs related to our Convertible Notes in May 2021 and subsequent write-off of additional issuance costs of $0.7 million upon conversion of the Convertible Notes at the time of the IPO in September 2021. Additionally, we incurred $2.8 million of interest expense during the period the Convertible Notes were outstanding. The termination of our revolving credit agreement required us to pay a fee of $1.3 million.

Change in Fair Value of Convertible Notes was $59.6 million and $0 for the years ended December 31, 2021 and 2020, respectively, reflecting fair value adjustments associated with the Convertible Notes issued by us in May 2021. We did not incur any gains or losses associated with changes in fair value of the Convertible Notes during the year ended December 31, 2020 as the Convertible Notes were not outstanding during that period.

Income Tax Expense increased to $32.8 million for the year ended December 31, 2021 from $0 for the year ended December 31, 2020, and our effective tax rate was 27.5% in the year ended December 31, 2021, compared to 0% for the year ended December 31, 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. The California Competes Tax Credit will be reflected as a benefit when certified annually which did not occur during the year ended December 31, 2021. Substantially all of our deferred tax assets continue to maintain a valuation allowance.

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 certain non-GAAP financial measures, adjusted net income and adjusted net income per diluted share, or adjusted diluted EPS. 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.

For the Years Ended December 31, 2021 and 2020

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.

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 and adjusted diluted EPS for the year ended December 31, 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.

The Convertible Notes issued by us in May 2021 were 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 assumptions 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.

In September 2021, our board of directors approved the forgiveness of certain promissory notes with our founders.

The reconciliations of net income (loss) (GAAP) and diluted EPS to adjusted net income (loss) (non-GAAP) and adjusted diluted EPS were calculated as follows for the years ended December 31, 2021 and 2020:

	Year Ended December 31,			
	2021		2020	
	Dollar Amount	Per Diluted Share	Dollar Amount	Per Diluted Share
Net income (loss)/diluted EPS	$ 86,418	0.59	$ (47,352)	(2.90)
Fair value adjustments of convertible notes	59,560	0.47	—	—
Banking and financing-related items	7,998	0.07	—	—
Forgiveness of promissory notes[(1)]	12,880	0.10	—	—
Tax effects[(2)]	(2,315)	(0.02)	—	—
Adjusted net income (loss)/adjusted diluted EPS	$ 164,541	$ 1.21	$ (47,352)	$ (2.90)

(1) Represents stock-based compensation expense related to the forgiveness of promissory notes subject to restricted stock purchase agreements with certain executives. The forgiveness of the promissory notes resulted in the modification of the stock option accounting applied to the shares underlying these agreements. See Note 12, *Stock-Based Compensation*, to our audited financial statements included elsewhere in this annual report.

(2) Represents the tax impact with respect to the adjustments noted above. We applied the effective tax rate of 27.5% to amounts deductible for tax purposes to quantify the tax effects. The charges related to the convertible notes and the portion of the forgiveness of promissory notes limited by Internal Revenue Code Section 162(m) were not deductible for income tax purposes and were excluded from the tax effects above. Also includes additional tax effects related to banking and financing-related items that became deductible upon the IPO during the year ended December 31, 2021.

Liquidity and Capital Resources

Overview

As of December 31, 2021, we held $409.9 million of cash and cash equivalents as a result of our IPO proceeds and other financing activities. Our primary cash needs are for the funding of day-to-day operations, financing capital investments and to address our working capital needs. Our largest source of operating cash generation is from sales to our customers. Our primary uses of cash from operating activities are for personnel-related expenses, material and supply costs

for manufacturing, direct costs to deliver our products, and sales and marketing expenses and research and development initiatives.

Based on our current business plan, we believe our anticipated operating cash flows, together with our existing cash and cash equivalents, 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 expansion of our research and development capabilities, expanding production capacity and optimization of existing business processes.

Revolving Line of Credit

In February 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 Revolving Credit Agreement provided 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. In June 2021, we terminated the Revolving Credit Agreement and we were required to pay a fee equal to 1.00% of the amount of the outstanding revolving commitment. Upon agreement with East West Bank and the other lenders to the Revolving Credit Agreement, we are keeping in place our outstanding letter of credit in the amount of $12.0 million, which will be cash collateralized. In November 2021, East West Bank increased the letter of credit by $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

Cash Flows

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

	Year Ended December 31,	
	2021	**2020**
(dollars in thousands)		
Net cash, cash equivalents and restricted (used in) provided by operating activities	$ (9,449)	$ 92,655
Net cash, cash equivalents and restricted cash used in investing activities	(115,717)	(78,148)
Net cash, cash equivalents and restricted cash provided by financing activities	419,621	100,243
Net increase in cash, cash equivalents and restricted cash	$ 294,455	$ 114,750

Cash Flows Used in Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was $9.4 million for the year ended December 31, 2021, primarily due to increases in accounts receivable and inventory of $100.4 million, and $51.5 million respectively. Non-cash deferred revenue of $90.6 million was recognized during the period. The timing of our revenue, timing of our collections, and an increase in private sector customers increased our accounts receivable. The expected increase in demand for our products drove the increase in inventory. These outflows were offset by non-cash cost adjustments, primarily driven by the change in fair value of the Convertible Notes of $59.6 million, depreciation and amortization expenses of $32.5 million and stock-based compensation expense of $43.0 million.

Net cash, cash equivalents and restricted cash provided by operating activities was $92.7 million for the year ended December 31, 2020, primarily due to an increase in government funding of $183.1 million. The increase was primarily offset by the use of cash in inventory and prepaid expenses and other current assets of $36.8 million, and $31.0 million, respectively, related to the commencement of product manufacturing and expansion of production facilities and manufacturing capacity.

Cash Flows Used in Investing Activities

Net cash, cash equivalents and restricted cash used in investing activities was $115.7 million for the year ended December 31, 2021, reflecting purchases of property and equipment of $108.8 million. The purchases of property and equipment were used to expand our production capabilities of our Cue COVID-19 Test Kits in relation to the U.S. DoD Agreement and our commercial customers. We also invested $6.9 million in the development of software related to COVID-19 Testing apps for commercial customers.

Net cash, cash equivalents and restricted cash used in investing activities was $78.1 million for the year ended December 31, 2020, reflecting purchases of property and equipment of $76.0 million to expand our production capabilities of Cue COVID-19 Test Kits in relation to the U.S. DoD agreement. We also invested $2.1 million in the development of internal-use software related to COVID-19 Testing apps for commercial customers.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2021 of $419.6 million was primarily driven by $206.0 million in net proceeds from our IPO and $235.5 million in gross proceeds from the issuance and sale of Convertible Notes.

Net cash, cash equivalents and restricted cash provided by financing activities was $100.2 million for the year ended December 31, 2020, primarily reflecting proceeds received from our issuance of Series C redeemable convertible preferred stock in June 2020.

Commitments and Contingencies

See Note 15, *Commitments and Contingencies*, to our audited financial statements included elsewhere in this annual report for a summary of our commitments as of December 31, 2021. Our material cash commitments at December 31, 2021 related to finance leases of manufacturing equipment totaling $6.0 million, real estate leases under non-cancelable operating lease agreements in the amount of $68.8 million, that expire at various dates through 2031 and a legal settlement of a contract dispute totaling $9.0 million, of which $4.5 million has not been paid. We expect to fund these commitments using our existing cash on hand.

As of December 31, 2020, the Company was party to certain letters of credit, primarily related to a letter of credit with Comerica Bank as collateral required by one of the Company's vendors. During the year ended December 31, 2021, the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the letters of credit were no longer required by the counterparties. The one letter of credit, totaling $6.0 million, has been 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 letter of credit in the amount of $6.0 million. The letter of credit was increased to $12.0 million in July 2021. In November 2021 East West Bank increased the letter of credit by $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated. In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports. The Company also has outstanding, letters of credit with Comerica Bank related to its real estate leases totaling $0.5 million as of December 31, 2021. All letters of credit are collateralized.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements included elsewhere in this Form 10-K that have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported income generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. While our significant accounting policies are more fully described in Note 2 to our audited financial statements, included elsewhere in this Form 10-K, we believe that the accounting policies discussed below are critical to

understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

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. Estimates of a future contract include future pricing, quantities and the timing and duration of future contracts. Estimates for standalone selling price are done at contract inception and are not subsequently updated. Changes in estimates are done on a prospective adjustment approach and the Company reassess its estimate on a quarterly basis. Changes in the assumptions used in our estimate of the future contract with the U.S. DoD, may have a material impact on the timing of recognition of deferred revenue.

A 10% increase or decrease in our projection of quantities purchased by the U.S. DoD under a follow-on agreement, holding all other assumptions constant, would increase or decrease the deferred revenue we recognized in the quarter ended December 31, 2021 by less than $2.5 million. A 10% increase or decrease in our projection of future pricing under a follow-on agreement, holding all other assumptions constant, would increase or decrease the deferred revenue we recognized in the quarter ended December 31, 2021 by less than $4.2 million.

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 December 31, 2021, we continue to maintain a valuation allowance against our U.S. federal and state deferred tax assets. The valuation allowance will be reduced at such time as management believes it is more-likely-than-not that the deferred tax assets will be realized. The exact timing and amount of a valuation allowance release are subject to change on the basis of the future level of profitability and changes in tax law. 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.

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, 2021 and 2020, the product warranty reserve was $4.9 million and $0, respectively.

A 10% increase or decrease in our failure rate estimate during 2021, holding all other assumptions constant, would increase or decrease the product warranty reserve by approximately $0.6 million. A 10% increase or decrease in our replacement rate estimate during 2021, holding all other assumptions constant, would increase or decrease the product warranty reserve by approximately $0.5 million.

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 document.

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.

Item 7A. 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 December 31, 2021, we had cash, cash equivalents and restricted cash of $423.7 million primarily from net proceeds of our IPO and other financing activities. 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 year ended December 31, 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.

Item 8. Financial Statements and Supplementary Data

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, 2021 and 2020, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

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
March 29, 2022

Cue Health Inc.

BALANCE SHEETS
(In thousands, except share amounts and share data)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 409,873	$ 121,578
Restricted cash	13,837	6,000
Accounts receivable, net	104,589	4,168
Inventories	88,388	36,842
Prepaid expenses	45,889	13,847
Other current assets	7,446	1,263
Total current assets	670,022	183,698
Restricted cash, non-current	—	1,677
Property and equipment, net	177,456	103,683
Prepaid rent	1,567	16,771
Operating lease right-of-use assets	79,474	8,281
Intangible assets, net	7,673	2,038
Other non-current assets	3,868	180
Total assets	$ 940,060	$ 316,328
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 37,208	$ 23,847
Accrued liabilities and other current liabilities	29,498	8,822
Income taxes payable	8,297	—
Deferred revenue, current	82,165	115,747
Debt, current	—	5,434
Operating lease liabilities, current	7,147	797
Finance lease liabilities, current	2,621	1,249
Total current liabilities	166,936	155,896
Redeemable convertible preferred stock warrant liabilities	—	1,331
Deferred revenue, net of current portion	10,283	67,349
Operating leases liabilities, net of current portion	46,464	10,472
Finance lease liabilities, net of current portion	3,271	1,857
Other non-current liabilities	6,356	4,500
Total liabilities	233,310	241,405
Commitments and contingencies (Note 15)		

Redeemable Convertible Preferred Stock		
Series A redeemable convertible preferred stock, $0.00001 par value; no shares authorized, issued or outstanding at December 31, 2021 and 8,721,437 authorized, 8,350,743 issued and outstanding at December 31, 2020; liquidation preference of $0 at December 31, 2021 and $7,660 at December 31, 2020	—	7,519
Series B redeemable convertible preferred stock, $0.00001 par value; no shares authorized, issued or outstanding at December 31, 2021 and, 46,213,620 authorized, 46,176,715 issued and outstanding at December 31, 2020; liquidation preference of $0 at December 31, 2021 and $66,240 at December 31, 2020	—	66,186
Series C-1 redeemable convertible preferred stock, $0.00001 par value; no shares authorized, issued or outstanding at December 31, 2021 and 27,308,229 authorized, 27,308,227 issued and outstanding at December 31, 2020; liquidation preference of $0 at December 31, 2021 and $100,000 at December 31, 2020	—	96,436
Series C-2 redeemable convertible preferred stock, $0.00001 par value; no shares authorized, issued or outstanding at December 31, 2021 and 1,690,380 authorized, 1,690,380 issued and outstanding at December 31, 2020; liquidation preference of $0 at December 31, 2021 and $5,571 at December 31, 2020	—	6,182
Total redeemable convertible preferred stock	—	176,323
Stockholders' Equity (Deficit)		
Preferred stock, $0.00001 par value; 50,000,000 and no shares authorized, no shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.00001 par value; 500,000,000 and 129,030,355 shares authorized, 146,402,991 and 27,995,780 issued and outstanding at December 31, 2021 and December 31, 2020, respectively	1	—
Additional paid-in-capital	730,767	9,036
Accumulated deficit	(24,018)	(110,436)
Total stockholders' equity (deficit)	706,750	(101,400)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 940,060	$ 316,328

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.

STATEMENTS OF OPERATIONS
(In thousands, except per share amounts and share data)

	Year Ended December 31,		
	2021	**2020**	**2019**
Revenue			
Product revenue	$ 615,796	$ 15,391	$ —
Grant and other revenue	2,311	7,562	6,626
Total revenue	618,107	22,953	6,626
Operating costs and expenses:			
Cost of product revenue	276,542	14,951	—
Sales and marketing	28,729	714	88
Research and development	42,829	28,478	21,405
General and administrative	79,788	23,936	5,900
Total operating costs and expenses	427,888	68,079	27,393
Income (loss) from operations	190,219	(45,126)	(20,767)
Other income (expense):			
Interest expense	(9,809)	(374)	(152)
Change in fair value of redeemable convertible preferred stock warrants	53	(1,289)	4
Change in fair value of convertible notes	(59,560)	—	—
Loss on extinguishment of debt	(1,998)	(610)	—
Other income, net	272	47	309
Net income (loss) before income taxes	119,177	(47,352)	(20,606)
Income tax expense	32,759	—	—
Net income (loss)	$ 86,418	$ (47,352)	$ (20,606)
Net income (loss) per share attributable to common stockholders – basic	$ 0.63	$ (2.90)	$ (1.31)
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – basic	52,815,449	16,315,730	15,760,246
Net income (loss) per share attributable to common stockholders – diluted	$ 0.59	$ (2.90)	$ (1.31)
Weighted-average number of shares used in computation of net income (loss) per share attributable to common stockholders – diluted	59,635,384	16,315,730	15,760,246

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	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)

Cue Health Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (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	96,436	—	—	—	—	—
Conversion of convertible notes to Series C-2 preferred stock	—	—	—	—	1,690,380	6,182	—	—	—	—	—
Release of common stock from restricted stock purchase agreement	—	—	—	—	—	—	—	—	—	—	—
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)

Cue Health Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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' Equity (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 redeemable convertible preferred stock warrants	48,513	831	31,369	537	—	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock	(8,399,256)	(8,350)	(46,208,084)	(66,723)	(28,998,607)	(102,618)	83,605,947	1	177,690	—	177,691
Exercise of common stock options	—	—	—	—	—	—	1,500,071	—	432	—	432
Conversion of convertible notes into common stock	—	—	—	—	—	—	18,611,914	—	297,792	—	297,792
Stock-based compensation expense from issuance of a fully vested warrant to vendor	—	—	—	—	—	—	—	—	1,239	—	1,239
Issuance of common stock at public offering, net of issuance costs of $24.0 million	—	—	—	—	—	—	14,375,000	—	205,956	—	205,956
Exercise of common stock warrants	—	—	—	—	—	—	84,118	—	77	—	77
Vesting of early exercised stock options	—	—	—	—	—	—	—	—	152	—	152
Tax withholding on exercise of stock options and restricted stock units	—	—	—	—	—	—	—	—	(4,586)	—	(4,586)

Cue Health Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)

Common stock issued to outgoing directors	—	—	—	—	—	—	128,000	—	—	—	—
Vesting of restricted stock units	—	—	—	—	—	—	102,161	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	42,979	—	42,979
Net income	—	—	—	—	—	—	—	—	—	86,418	86,418
Balance at December 31, 2021	—	$ —	—	$ —	—	$ —	146,402,991	$ 1	$ 730,767	$ (24,018)	$ 706,750

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.

STATEMENTS OF CASH FLOWS
(In thousands, except share data)

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net income (loss)	$ 86,418	$ (47,352)	$ (20,606)
Adjustments to reconcile net income (loss) to net cash, cash equivalents and restricted cash (used in) provided by operations			
Depreciation and amortization	32,509	6,282	3,653
Change in fair value of redeemable convertible preferred stock warrant liabilities	(53)	1,289	(4)
Change in fair value of convertible notes	59,560	—	—
Stock-based compensation expense	42,979	3,163	336
Loss on extinguishment of debt	1,998	610	—
Non-cash lease expense	5,318	568	—
Convertible notes issuance costs	6,000	—	—
Deferred income taxes	3,468	—	—
Interest on finance leases	218	113	107
Stock-based compensation expense from issuance of fully vested warrant to vendor	1,239	—	—
Non-cash interest expense	2,883	16	6
Changes in operating assets and liabilities:			
Accounts receivable	(100,422)	(3,968)	4,291
Inventory	(51,546)	(36,842)	—
Prepaid expenses and other current assets	(38,987)	(30,978)	(415)
Other non-current assets	(3,688)	(130)	(374)
Accounts payable, accrued liabilities and other current liabilities	44,823	12,637	10
Income taxes payable	11,185	—	—
Deferred revenue	(90,648)	183,084	—
Operating lease liabilities	(18,203)	(337)	—
Other non-current liabilities	(4,500)	4,500	—
Net cash, cash equivalents and restricted cash (used in) provided by operating activities	(9,449)	92,655	(12,996)
Cash flows from investing activities			
Purchases of property and equipment	(108,848)	(76,034)	(2,945)
Expenditures for software development	(6,869)	(2,114)	—
Net cash, cash equivalents and restricted cash used in investing activities	(115,717)	(78,148)	(2,945)
Cash flows from financing activities			
Proceeds from issuance of Series C-1 redeemable convertible preferred stock	—	100,000	—
Proceeds from convertible notes	235,480	5,563	—
Payments for issuance costs of Series C-1 redeemable convertible preferred stock	—	(3,564)	—
Proceeds from exercise of redeemable convertible preferred stock warrant	89	—	—
Payments of issuance costs of convertible notes	(6,000)	—	—
Proceeds from exercise of common stock options	432	1,079	12

Proceeds from exercise of common stock warrant	77	—	—
Proceeds from issuance of common stock at public offering	230,000	—	—
Payments of issuance costs of public offering	(24,044)	—	—
Proceeds from debt	82,250	1,658	4,084
Tax withholding on exercise of stock options and restricted stock units	(4,586)	—	—
Debt issuance and prepayment costs	(2,128)	—	—
Repayment of debt	(87,684)	(2,571)	—
Payments for finance leases	(4,265)	(1,922)	(486)
Net cash, cash equivalents and restricted cash provided by financing activities	419,621	100,243	3,610
Net change in cash, cash equivalents and restricted cash	294,455	114,750	(12,331)
Cash, cash equivalents and restricted cash, beginning balance	129,255	14,505	26,836
Cash, cash equivalents and restricted cash, ending balance	$ 423,710	$ 129,255	$ 14,505
Reconciliation of cash, cash equivalents, and restricted cash			
Cash and cash equivalents	$ 409,873	$ 121,578	$ 14,328
Restricted cash, current	13,837	6,000	—
Restricted cash, non-current	—	1,677	177
Total cash, cash equivalents and restricted cash	$ 423,710	$ 129,255	$ 14,505
Supplemental disclosure for cash flow information			
Cash paid for taxes	$ 18,106	$ —	$ —
Cash paid for interest	$ 767	$ 340	$ 152
Supplemental disclosure for non-cash investing and financing matters			
Early exercised stock options liability	$ 152	$ 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	$ 48,211	$ 11,269	$ —
Prepaid rent reclassified to right-of-use assets	$ 15,966	$ —	$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 6,765	$ 18,156	$ 110
Software development costs included in accounts payable	$ 758	$ —	$ —
Conversion of redeemable convertible preferred stock into common stock	$ 177,691	$ —	$ —
Exercise of redeemable convertible preferred stock warrant	$ 1,278	$ —	$ —
Conversion of convertible notes	$ 297,792	$ —	$ —
Equipment obtained under capital lease obligations	$ —	$ —	$ 346

The accompanying notes are an integral part of these financial statements.

Cue Health Inc.

NOTES TO FINANCIAL STATEMENTS
(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.

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") and the rules and regulations of the Securities and Exchange Commission ("SEC") for reporting.

Initial Public Offering

On September 28, 2021, the Company completed its initial public offering ("IPO") of 14,375,000 shares of the Company common stock at an offering price of $16.00 per share, including 1,875,000 shares purchased by the IPO underwriters. The Company received aggregate net proceeds of approximately $206.0 million after deducting underwriting commissions and legal, accounting, and consulting fees related to the IPO.

Upon completion of the IPO, Convertible Notes outstanding, see Note 9, *Debt*, in the principal amount of $235.5 million and accrued interest of $2.8 million were automatically converted into 18,611,914 shares of common stock. All outstanding shares of the Company's redeemable convertible preferred stock, see Note 10, *Capital Stock*, were converted into 83,605,947 shares of common stock. Immediately prior to the IPO, all of the Company's outstanding warrants to purchase redeemable convertible preferred stock were converted into the redeemable convertible preferred stock and the related warrant liabilities were reclassified to additional paid-in capital.

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.

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to revenue recognition, net accounts receivable, stock-based compensation expense, product warranty reserve, the recoverability of its long-lived assets, net deferred tax assets (and related valuation allowance) and the fair value of Convertible Notes and common stock prior to the Company's IPO. 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

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 revenues 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 product revenues are 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 various emergency use authorizations for 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

Cash and cash equivalents consist of bank deposits. 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. As of December 31, 2021 and 2020, the Company had $13.8 million and $7.7 million of restricted cash included on the balance sheets.

Accounts Receivable

The Company grants credit to customers in the normal course of business and the resulting accounts receivable is stated at their net realizable value. The allowance for doubtful accounts represents the Company's estimate of probable credit losses relating to accounts receivable and is determined based on historical experience and other specific account data. Amounts are written off against the allowances for doubtful accounts when the Company determines that a customer account is uncollectible. As of December 31, 2021 and 2020, the Company's allowance for doubtful accounts was $0.3 million and $0, respectively.

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, 2021, at 62% and 25%, respectively. For the year ended December 31, 2020, the Company had two customers that represented more than 10% of product revenue 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, 2021, accounts receivable from one customer with balances due in excess of 10% of total accounts receivable was 60%. 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 two single suppliers. 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. 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.

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 choose to replace Cue Cartridges that result in cancelled tests and invalid test results. All warranties are classified as current liabilities within the accrued liabilities and other current liabilities on the balance sheet. Provisions for estimated expenses related to product warranty are made at the time products are sold. These estimates are determined based on historical information that includes test failure rates, replacement frequency, and the overall replacement cost. 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 following table provides a reconciliation of the change in estimated warranty liabilities:

	Amount
Balance, December 31, 2020	$ —
Provision for warranties	7,744
Settlements	(2,879)
Balance, December 31, 2021	$ 4,865

The Company did not have a product warranty reserve for the years ended December 31, 2020 and 2019.

Fair Value Measurements and Financial Instruments

The carrying value of the Company's cash and cash equivalents, accounts receivable 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 1 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, see Note 11, *Fair Value Measurements*. 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, furniture and fixtures, 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
Machinery and equipment	3-7 years
Furniture and fixtures	7
Computers and software	3-5 years

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 certain 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, Net

Intangible assets, net 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 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.

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. 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.

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.

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 statements of operations. As of December 31, 2021, the deferred offering costs were offset against the proceeds received upon the completion of the IPO. There were no deferred offering costs recorded in the Company's balance sheets as of December 31, 2020.

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, 2021, 2020 and 2019.

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. All of the Company's outstanding redeemable convertible preferred stock warrants were exercised and converted into shares of Series A and Series B redeemable convertible preferred stock prior to the IPO.

Redeemable Convertible Preferred Stock

Prior to the completion of the IPO, the Company had multiple classes of redeemable convertible preferred stock, all of which were classified as temporary equity in the accompanying balance sheet as the redemption of the shares were outside of the Company's control.

In connection with the completion of the IPO in September 2021, all outstanding shares of redeemable convertible preferred stock were automatically converted into an aggregate of 83,605,947 shares of common stock.

Revenue Recognition

Product Revenue

The Company generates revenue from the sale of its products to government entities, healthcare providers, commercial customers, distributors, and direct-to-consumer ("DTC") sales.

The Company considers purchase orders, which are governed by agreements with customers other than DTC customers, to be a contract with a customer. The contract terms with customers, other than DTC, range in length, from one-time purchases to six-month or twelve-month commitments on a subscription basis where customers purchase a fixed number of products on a monthly basis. DTC sales are conducted via the Company's website where customers can purchase individual products or subscribe to Cue+ Memberships. The Company considers the DTC customers' agreement to the terms and conditions at the point of purchase to be a contract with a customer.

Cue Readers, Cue Enterprise Dashboards, and Cue Test Kits, composed of Cue Cartridges and Cue Wands, are considered distinct performance obligations. The App is integral to the functionality of the Cue Reader and these two 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 Cue Enterprise Dashboards is recognized ratably over the term of the service.

The Company's contracts with its customers do not provide for open return rights. The Company estimates returns of products due to defective or nonconforming Cue Readers and replacement Cue Cartridges and records a provision for estimated expenses related to product warranty at the time products are sold.

In addition to the above performance obligations, Cue+ Memberships include service components comprised of virtual care capabilities accessible through the App. The Cue+ Essential membership provides telemedicine (access to chat with board-certified physicians) and the Cue+ Complete membership also includes video proctoring of tests.

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.

To fulfill its promise to customers for contracts that include telemedicine, the Company maintains relationships with medical service providers, which are professional corporations or other professional entities owned by licensed physicians that engage licensed medical professionals (medical doctors, physician assistants, and nurse practitioners; collectively referred to as "Providers") to provide telemedicine services. The Company determined that it is an agent in the telemedicine arrangement with its customers because (i) the Providers determine which specific medical services are to be provided during the consultation and (ii) the Providers are primarily responsible for the satisfactory fulfillment and acceptability of the services. As an agent in the telemedicine portion of the contract, the Company recognizes the revenue allocated to the service net of the costs incurred to deliver the service. Revenue from telemedicine services is recognized at a point in time at the inception of the contract with a customer.

To fulfill its promise to customers for contracts that include proctoring services, the Company maintains relationships with service providers to provide proctoring services. The Company determined that it a principal in the proctoring arrangement with its customers because (i) the Company determines which services are to be provided to the customer; (ii) the Company is primarily responsible for the satisfactory fulfillment and acceptability of the services; and (iii) the Company, at its sole discretion, sets all listed prices charged on its website for products and services. Revenue from proctoring services is recognized over the term of the agreement.

The Company recognizes 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 to 45 days. No adjustments to consideration are made for financing as the Company expects, at contract inception, that the period between the transfer of a promised good or service and when the customer pays for that good or service will be one year or less.

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.

See Note 3, *Revenue Recognition*, for details regarding disaggregation of product revenue by type of customer for the years ended December 31, 2021, 2020 and 2019.

Deferred Revenue

In October 2020, the Company received a $184.6 million upfront payment ("U.S. DoD Advance") from the U.S. DoD 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 a 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 the Company receives grants or contracts to conduct research and development activities constitute non-exchange transactions. Revenue from non-exchange transactions is recognized to the extent of costs incurred in the period, 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.

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 (Topic 606)* ("ASC 606").

See Note 3, *Revenue Recognition*, for details regarding the Company's agreements with the Biomedical Advanced Research and Development Authority ("BARDA" and Janssen Pharmaceuticals, Inc. ("Janssen").

Contract Assets and Liabilities

Contract assets primarily relate to the Company's conditional right to consideration for performance obligations satisfied through direct-to-consumer sales but not billed at the reporting date. Contract assets at the beginning of and end of the year ended December 31, 2021, as well as changes in the balance, 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. See Note 3, *Revenue Recognition*, for details regarding the activity related to contract liabilities.

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 as 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, advertising costs and business development functions. Advertising costs are expensed as incurred.

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 expenses consists primarily of salaries and other related costs, including stock-based compensation, for personnel in its executive, finance, and administrative functions. General and administrative expense also includes professional fees for legal, patent, accounting, information technology, auditing, tax and consulting services, travel expenses as well as depreciation 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

Prior to the IPO, 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 allow for any vesting schedule as the Company's Board of Directors may deem appropriate. The Compensation Committee with oversight from Board of Directors determines the number of shares, the term, the frequency and date, the type, the exercise periods, any performance criteria pursuant to which awards may be granted, and the restrictions and other terms and conditions of each grant in accordance with terms of the plan. 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.

The fair value of restricted stock units (RSUs) is determined based on the fair value of the Company's common stock at the grant date. The RSUs generally have a vesting term of four years. For RSUs with performance-based vesting conditions, compensation cost is recognized when it is probable that the performance criteria will be achieved. For RSUs with market-based vesting conditions, compensation cost is based on the fair value of the award at grant date and recorded over the requisite service period. Compensation cost is not adjusted if the market condition is not met, as long as the requisite service is provided. The Company estimates the fair value of stock-based payment for awards with market conditions on the date of grant using a Monte Carlo simulation model.

Comprehensive Income (Loss)

Comprehensive income (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 income (loss) and, therefore, the Company's comprehensive income (loss) was the same as its reported net income (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 bases 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.

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. 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.

In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other - Internal Use Software (Subtopic 350-40) - Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract. ASU 2018-15 amends the definition of a hosting arrangement and requires a customer in a hosting arrangement that is a service contract to capitalize certain implementation costs as if the arrangement was an internal-use software project. The internal-use software guidance states that only qualifying costs incurred during the application development stage can be capitalized. The Company adopted ASU 2018-15 effective January 1, 2021. As of December 31, 2021, $3.4 million of implementation costs for cloud computing arrangements were capitalized, net of accumulated amortization, primarily related to implementation of the Company’s enterprise resource planning system and customer relationship management system, among other software implementations. These costs were recorded in other non-current assets in the balance sheets.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes (“ASU 2019-12”). 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.

New Accounting Pronouncements Not Yet Adopted

In September 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326) – Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). 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 2016-13 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 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 Company is currently evaluating the impact of ASU 2020-06 on its financial statements.

NOTE 3. REVENUE

Product Revenue

Disaggregation of product revenue by type of customer for the years ended December 31, 2021, 2020, and 2019 respectively:

	Year Ended December 31,		
	2021	**2020**	**2019**
Public sector entities	$ 382,958	$ 8,874	$ —
Private sector customers	232,838	6,517	—
Total product revenue	$ 615,796	$ 15,391	$ —

Product revenue for the year ended December 31, 2021 includes an immaterial amount of service revenue generated from telemedicine and proctoring services provided to customers. Revenue generated from proctoring is recognized over the term of the contracts with customers.

The following table sets forth the Company's product gross profit and product gross profit margin for the years ended December 31, 2021, 2020, and 2019:

	Year Ended December 31,		
	2021	**2020**	**2019**
Product revenue	$ 615,796	$ 15,391	$ —
Cost of product revenue	276,542	14,951	—
Product gross profit	$ 339,254	$ 440	$ —
Product gross profit margin	55 %	3 %	0%

DoD Agreement

In October 2020, the Company entered into a $480.9 million 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"). The Company delivered all of the agreed upon products under the agreement prior to its expiration on December 31, 2021. 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. The U.S. DoD Agreement did not provide for the funds to be utilized in any specific manner beyond furthering the purposes of the agreement. The Company was not required to segregate, nor was the Company required to obtain the approval of the U.S. government to use the funds advanced to us under the agreement. The remaining $296.3 million of the agreement was due to the Company for the delivery of Cue Readers, Cue COVID-19 Test Kits and Cue Control Swab Packs. The U.S. DoD Agreement also provided that, as soon as possible after the completion of the initial U.S. DoD Agreement, the Company and the U.S. government would negotiate in good faith to enter into a follow-on supply agreement based on federal acquisition regulations (a FAR-based contract). The U.S. DoD 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 was required to 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 was entitled to be the exclusive purchaser of our entire production through the completion of the project. Pursuant to the U.S. DoD Agreement, the Company was permitted to honor certain contractual obligations that existed prior to the effective date of the U.S. DoD Agreement and to 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, the Company was able to seek waivers from the U.S. government to sell certain of our products to additional customers. The agreement term ended upon completion of the Company's performance obligations in December 2021.

The Company determined that the U.S. DoD Agreement is within the scope of ASC 606. The delivery of the individual Cue COVID-19 Test products are distinct performance obligations since they are capable of being distinct and are distinct within the context of 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. The U.S. government continues to maintain such material right that is applicable to a future contract. 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, 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 the stand-alone selling price for each performance obligation and allocated the total transaction price on a relative standalone selling price basis to each performance obligation. 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 Agreement would be included in any follow-on contract. The U.S. DoD Advance was recorded in deferred revenue and is recognized in revenue as the related performance obligations are satisfied. Estimates of a future contract include future pricing, quantities and the timing and duration of future contracts. Changes in estimates are done on a prospective adjustment approach and the Company reassess its estimate quarterly. 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, 2021 and 2020, was $92.4 million and $182.3 million, respectively. Of this amount, $82.2 million is classified as current as of December 31, 2021, based on amounts expected to be realized within the next year.

Contract Assets and Liabilities

Net contracts assets were $1.1 million and $0 as of December 31, 2021 and 2020, respectively, and were recorded in other current assets on the balance sheets.

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 years ended December 31, 2021 and 2020, is as follows:

	Amount
Balance at December 31, 2019	$ 12
U.S. DoD Advance	184,577
Non-refundable customer deposits	803
Recognition of U.S. DoD Advance	(2,296)
Balance at December 31, 2020	183,096
Recognition of U.S. DoD Advance	(89,845)
Recognition of non-refundable customer deposits	(803)
Balance at December 31, 2021	$ 92,448

Grant and Other Revenue

Grant and other revenue relate to a cost reimbursement agreement with the BARDA and a collaboration agreement with Janssen.

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 was to accelerate the development, validation, regulatory authorization and commercialization of the Company’s products. The BARDA Contract required the Company provide reporting deliverables that included monthly technical and annual reports and a final report, but BARDA was 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.

In December 2021, the original BARDA Contract was amended to fund an additional $0.8 million for the development of an Omicron-Genotyping COVID-19 test.

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. The Company recorded $2.2 million, $7.6 million and $6.3 million of revenue related to the agreement with BARDA during the years ended December 31, 2021, 2020 and 2019, respectively.

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 and the Company owns all resulting intellectual rights. Revenue from the Janssen Contract was recorded over time on an input method as costs were incurred. Costs incurred during 2019 are included in research and development expenses. There was no activity related to this agreement during the years ended December 31, 2021 and 2020.

NOTE 4. INVENTORIES

As of December 31, 2021 and 2020, the Company's inventories consisted of the following:

	December 31,	
	2021	2020
Raw materials	$ 34,042	$ 31,029
Work-in-process	10,920	4,957
Finished goods	46,094	1,645
Reserve	(2,668)	(789)
Total inventories	$ 88,388	$ 36,842

NOTE 5. PREPAID EXPENSES

As of December 31, 2021 and 2020, the Company's prepaid expenses consisted of the following:

	December 31,	
	2021	2020
Prepaid expense	$ 30,153	$ 5,152
Prepaid inventory	15,736	8,695
Total prepaid expenses	$ 45,889	$ 13,847

NOTE 6. PROPERTY AND EQUIPMENT, NET

As of December 31, 2021 and 2020, the Company's property and equipment, net consisted of the following:

	December 31,	
	2021	2020
Construction in progress	$ 4,082	$ 83,353
Machinery and equipment	195,001	26,972
Leasehold improvements	19,302	2,897
Furniture and fixtures	740	683
Property and equipment	219,125	113,905
Accumulated depreciation and amortization	(41,669)	(10,222)
Total property and equipment, net	$ 177,456	$ 103,683

Depreciation and amortization expense related to property and equipment was $30.5 million, $6.2 million and $3.7 million for the years ended December 31, 2021, 2020 and 2019, respectively. The carrying value of assets under finance leases within property and equipment as of December 31, 2021 and 2020 was $9.8 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, 2021 and 2020, the Company's intangible assets consisted of the following:

	December 31,	
	2021	2020
Capitalized software	$ 5,638	$ 914
Accumulated amortization	(2,067)	(76)
Capitalized software, net	3,571	838
In-process software development	4,102	1,200
Total intangible assets	$ 7,673	$ 2,038

Amortization expense related to intangible assets placed in service was $2.0 million, $0.1 million, and $0 for the years ended December 31, 2021, 2020 and 2019, respectively. Estimated amortization expense for each of the years ending December 31 is as follows:

2022	$ 1,501
2023	1,453
2024	617
Total amortization expense	$ 3,571

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.

A summary of the Company's material leases is as follows:

Waples Lease. In June 2020, the Company entered into an agreement to lease an approximately 64,000 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 begin installation of manufacturing equipment. The Company paid $12.5 million for landlord-owned improvements recorded as prepaid rent. Upon commencement of the lease the prepaid rent was reclassified into the operating lease right-of-use asset. The Company recognized an 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 the commencement date.

Vista Lease. 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 paid $3.5 million for landlord-owned improvements recorded as prepaid rent. Upon commencement of the lease the prepaid rent was reclassified into the operating lease right-of-use asset. 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 the commencement date.

The right-of-use assets and lease liabilities recognized on the Company's balance sheets as of December 31, 2021 and 2020 were as follows:

	Balance Sheet Location	December 31, 2021	December 31, 2020
Assets			
Right-of-use assets operating leases	*Operating lease right-of-use assets*	$ 79,474	$ 8,281
Right-of-use assets finance leases	*Property and equipment, net*	9,821	4,837
Liabilities			
Operating lease liabilities (current)	*Operating lease liabilities, current*	7,147	797
Finance lease liabilities (current)	*Finance lease liabilities, current*	2,621	1,249
Operating lease liabilities (non-current)	*Operating lease liabilities, net of current portion*	46,464	10,472
Finance lease liabilities (non-current)	*Finance lease liabilities, net of current portion*	3,271	1,857

The components of lease cost for the years ended December 31, 2021 and 2020 were as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating lease cost	$ 7,983	$ 1,552
Finance lease cost:		
Amortization of right-of-use assets	1,854	570
Interest on lease liabilities	218	113
Total lease cost	$ 10,055	$ 2,235

Rent expense for the year ended December 31, 2019 was $0.9 million.

As of December 31, 2021, the maturities of the Company's operating and finance lease liabilities were as follows:

	Operating Leases	Finance Leases
2022	$ 7,147	$ 2,789
2023	7,384	2,408
2024	7,243	919
2025	7,424	—
2026	7,697	—
Thereafter	31,897	—
Total lease payments	68,792	6,116
Less: Imputed interest	(15,181)	(224)
Total	$ 53,611	$ 5,892

The supplemental cash flow information related to leases for the years ended December 31, 2021 and 2020 was as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 20,867	$ 1,287
Operating cash flows from finance leases	$ 218	$ 113
Financing cash flows from finance leases	$ 2,124	$ 1,922

Subsequent to the commencement dates of the Waples and Vista leases, the Company made cash payments of $17.0 million related to the ongoing construction of landlord-owned assets. This is presented in operating lease liabilities in the statements of cash flows.

The weighted-average remaining lease term and discount rate information related to operating and finance leases as of December 31, 2021 and 2020 was as follows:

	December 31, 2021		December 31, 2020	
	Operating Leases	Finance Leases	Operating Leases	Finance Leases
Weighted-average remaining lease term (in years)	8.9	2.3	8.4	2.5
Weighted-average discount rate	5.7%	3.8%	8.7%	6.5%

NOTE 9. DEBT

Revolving Credit Agreement

In February 2021, the Company entered into a loan and security agreement ("Revolving Credit Agreement") with a group of lenders with East West Bank, acting as administrative agent and collateral agent for the lenders. 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 subfacility of $20.0 million. In connection with entering into the Revolving Credit Agreement, the Company repaid outstanding amounts of $5.4 million and terminated an existing loan agreement with Comerica Bank.

In May 2021, the Company repaid $63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the proceeds from the issuance and sale of Convertible Notes. In June 2021, the Company terminated the Revolving Credit Agreement and was required to pay a termination fee of $1.3 million. 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 loss on extinguishment of debt in the statements of operations during the year ended December 31, 2021. All other obligations under the Revolving Credit Agreement have otherwise been terminated.

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 interest at a simple rate of 9.0% per annum thereafter.

The Company elected to account for the Convertible Notes at estimated fair value, see Note 11, *Fair Value Measurements*, pursuant to the fair value option and record the change in estimated fair value in the statement of operations. The Company recorded a loss of $59.6 million related to the change in estimated fair value of the Convertible Notes in its statement of operations for the year ended December 31, 2021. All of the Convertible Notes were converted upon the IPO, which was a qualified conversion event. The Convertible Notes' principal of $235.5 million and accrued interest of $2.8 million was converted into 18,611,914 shares of common stock at a fair value of $297.8 million using a 20% discount to the initial public offing price of $16.00 per share. The Company no longer had outstanding Convertible Notes as of December 31, 2021.

NOTE 10. CAPITAL STOCK

Amended and Restated Certificate of Incorporation

In September 2021, the Company's board of directors approved and the Company filed its restated amended certificate of incorporation, which authorized the issuance of up to 550,000,000 shares consisting of 500,000,000 shares of common stock and 50,000,000 shares of preferred stock with a par value of $0.00001 per share, respectively.

Preferred Stock

The Company's certificate of incorporation, as amended, authorizes the issuance of up to 50,000,000 preferred shares. The Board of Directors is authorized to fix the number of shares of any series of preferred stock and determine the

designations of such shares including but not limited to voting powers, dividend rights, liquidation preferences, and conversion rights. No shares of preferred stock were outstanding as of December 31, 2021 and 2020.

Redeemable Convertible Preferred Stock

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 were exercisable at a 10% discount (within 30 days) or 15% discount (after 45 days) upon a financing transaction in excess of $30.0 million. In connection with the closing of the IPO, the Convertible Notes were converted into 18,611,914 shares of common stock.

In June 2020, the Company raised $105.6 million in gross 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 into 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.

In connection with the closing of the IPO, all outstanding shares of redeemable convertible preferred stock were converted into 83,605,947 shares of common stock.

Redeemable Convertible Preferred Stock Warrants

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 11, *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.

Prior to September 2021, the Company had outstanding warrants to purchase 84,118 redeemable convertible preferred shares. Immediately prior to the IPO, in September 2021, all outstanding warrants were exercised and converted into shares of Series A and Series B redeemable convertible preferred stock. The related liability was derecognized upon exercise and recorded in equity.

Common Stock Warrants

As of December 31, 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. All shares subject to the warrant were vested as of December 31, 2020.

NOTE 11. 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, 2020	**Recurring Fair Value Measurements**			
	Level 1	**Level 2**	**Level 3**	**Total**
Redeemable convertible preferred stock warrant liabilities	$ —	$ —	$ 1,331	$ 1,331

There are no instruments that were measured at fair value on a recurring basis as of December 31, 2021.There were no transfers between Level 1, Level 2 and Level 3 categories of the fair value hierarchy during the years ended December 31, 2021 and 2020.

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 weighting 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 December 31, 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 December 31, 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 closing of the IPO was considered a qualified conversion event per the terms of convertible notes. As a result, the Convertible Notes, $235.5 million of principal and $2.8 million of accrued interest through September 27, 2021, were converted into 18,611,914 shares of common stock at a 20% discount to the initial public offing price of $16.00 per share. The Company recognized a loss of $59.6 million resulting from the conversion which was recorded in change in fair value of Convertible Notes in the statements of operations for the year ended December 31, 2021.

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, 2018	$ 46	$ —
Remeasurement	(4)	—
Balance, December 31, 2019	42	—
Remeasurement	1,289	—
Balance, December 31, 2020	1,331	—
Issuance	—	235,480
Remeasurement	(53)	59,560
Accrued interest	—	2,752
Exercise of redeemable convertible preferred stock warrants	(1,278)	—
Conversion into common stock	—	(297,792)
Balance, December 31, 2021	$ —	$ —

No redeemable convertible preferred stock warrants were outstanding as of December 31, 2021. 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 2019 :

Series A Redeemable Convertible Preferred Stock Warrants

	2020	2019
Expected volatility	59.9%	41.8%
Expected term (years)	4.92	5.92
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.41%	1.72%
Fair value per share	$ 16.83	$ 0.55

Series B Redeemable Convertible Preferred Stock Warrants

	2020	2019
Expected volatility	46.2%	37.2%
Expected term (years)	7.91	8.91
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	0.65%	1.88%
Fair value per share	$ 16.41	$ 0.68

NOTE 12. STOCK-BASED COMPENSATION

Stock Incentive Plans

2014 Equity Incentive Plan

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 incentive stock options, nonqualified stock options, stock appreciation rights, performance shares, awards of restricted stock and awards of restricted stock units.

As of December 31, 2021, with the introduction of a new stock incentive plan, shares are no longer available for future grants under the 2014 Plan.

2021 Stock Incentive Plan

In September 2021, the Company adopted the 2021 Stock Incentive Plan ("2021 Plan") under which employees, officers and directors, as well as consultants and advisors to the Company are eligible to be granted awards (incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards). The authorized number of shares includes 14,173,771 common shares plus such additional number of shares of common stock up to 22,399,691 as equal to the number shares reserved in the 2014 Plan above. The number of common stock shares available under the 2021 Plan increases annually on the first day of each fiscal year commencing January 1, 2022 until and including January 1, 2031 by the amount equal to at least 5% of outstanding shares on such date and any additional shares of common stock determined by the board. As of December 31, 2021, 56,695,085 shares of common stock are available for issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In September 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP") under which employees of the Company can purchase shares of the Company's common stock commencing on such time and such dates as the board of directors of the Company determine. The number of shares of common stock that have been approved for the purpose is 2,834,754 shares of common stock plus an annual increase to be added on the first day of each fiscal year commencing January 1, 2022 and continuing for each fiscal year until and including January 1, 2032. The annual increase is equal to the least of 8,504,263 shares of common stock, 1% of outstanding shares on such date, and a number of shares of common stock determined by the board of directors. The price at which stock is purchased under the 2021 ESPP is equal to 85% of the fair market value of the Company's common stock on the lesser of either (i) the first business day of the Plan Period or (ii) the Exercise Date.

Stock-Based Compensation

Stock-based compensation expense related to awards issued under the Company's incentive compensation plans for the years ended December 31, 2021, 2020, and 2019 was as follows:

	Year Ended December 31,		
	2021	2020	2019
Cost of revenues	$ 1,979	$ —	$ —
Sales and marketing	2,634	1	—
Research and development	6,889	98	45
General and administrative	31,477	3,064	291
Total stock-based compensation expense	$ 42,979	$ 3,163	$ 336

In total, $2.0 million and $0.0 million of stock-based compensation expense was capitalized to inventory during the manufacturing process during the years ended December 31, 2021 and 2020, respectively. An immaterial amount remained in inventory as of December 31, 2021. The Company incurred additional stock-based compensation expenses of $1.2 million related to the issuance of a fully-vested option valued at $1.2 million.

Stock Options

A summary of stock option activity and related information for the year ended December 31, 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	6.4
Granted	2,965,821	15.61	
Exercised	(1,713,054)	0.31	
Forfeited	(367,317)	10.58	
Expired	(67,042)	0.36	
Outstanding at December 31, 2021	9,163,160	$ 5.13	6.9
Exercisable at December 31, 2021	6,241,942	$ 2.01	6.0
Vested and expected to vest at December 31, 2021	9,163,160	$ 5.13	6.9

The aggregate intrinsic value of exercisable options was $72.4 million, $96.0 million and $0.8 million, for the years ended December 31, 2021, 2020 and 2019, respectively. The aggregate intrinsic value of stock options outstanding was $81.9 million, $129.5 million and $0.9 million as of December 31, 2021, 2020 and 2019, respectively.

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 years ended December 31, 2021, 2020 and 2019:

	2021	2020	2019
Expected volatility	40.9%	39.6%	28.4%
Expected term (years)	7.71	7.04	6.08
Expected dividend yield	0.0%	0.0%	0.0%
Risk-free interest rate	0.8%	0.4%	1.8%
Grant date fair value	$ 6.93	$ 0.57	$ 0.15

As of December 31, 2021, there was $14.6 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 2.81 years, on a straight-line basis.

Restricted Stock Units

Under the 2014 and 2021 Plans, RSUs are generally subject to a 4-year vesting period, with 25% of the shares vesting one year from the vesting commencement date and quarterly thereafter over the remaining vesting term, but may be subject to other vesting conditions such as performance or market based conditions. Compensation expense is recognized ratably over the requisite service period.

During the year ended December 31, 2021, the Company issued a total of 1,177,043 restricted stock units ("RSUs") to certain executives under the 2014 Plan with the right to receive common stock shares upon vesting as scheduled per agreements with certain executives. No additional grants of RSUs are expected under the 2014 Plan.

During the year ended December 31, the Company issued 10,535,637 RSUs to employees under the 2021 Plan of which 5,603,065 vest based solely on continued employment over a four year period and the remaining RSUs are also subject to performance-vesting conditions as described below.

Total RSU activity for the year ended December 31, 2021 is as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	—	$ —	$ —
Granted	11,584,681	14.65	169,716
Vested	(193,933)	15.65	(3,036)
Forfeited	(126,513)	16.00	(2,024)
Outstanding, December 31, 2021	11,264,235	$ 14.62	$ 164,656

In addition to the RSU activity above, 128,000 fully vested shares of common stock were granted to outgoing members of the board of directors in 2021. Recipients are prohibited from selling or otherwise transferring the shares for one year after the date of grant.

As of December 31, 2021 there was approximately $146.0 million of total unrecognized compensation cost related to outstanding RSUs.

Market-Based Performance-Vesting RSUs

In September 2021, the Company issued 3,335,300 RSUs that vest based on the satisfaction of both a continued employment condition and the achievement of certain market-based performance goals. Market-based performance-vesting RSUs vest upon the achievement of certain stock price performance over a performance period. There are seven stock price targets which can be achieved over the performance period and are based on an average closing price of the Company's common stock.

The fair value of the market-based performance-vesting RSU awards is based on a Monte-Carlo simulation with the following assumptions.

	For the year ended December 31, 2021
Expected dividend yield [(1)]	0.00 %
Risk-free interest rate [(2)]	1.27 %
Expected volatility [(3)]	65.00 %
Cost of equity [(3)]	0.15

(1) Dividend yield is based on no dividend payout being expected on common units over the term to expiration of the performance-vesting RSUs
(2) The risk-free interest rate for the periods within the contractual term of the market-based performance-vesting RSUs is based on the US Treasury yield curve in effect at the time of the grant.
(3) The expected volatility and cost of equity are measures of the amount by which a stock price has fluctuated or is expected to fluctuate based primarily on our and our peers' historical data.

The Company applied a 14% discount for lack of marketability ("DLOM") to the value of the market-based performance-vesting RSUs to account for a one-year post vesting period during which the grantee must hold the vested RSUs. The Company utilized the Finnerty Model to calculate the DLOM using inputs, including length of holding period,

volatility and dividend yield, with volatility considered as a significant Level 3 input in the fair value hierarchy. Stock price performance goals were not achieved as of December 31, 2021.

Market-based performance-vesting RSU activity for the year ended December 31, 2021 is as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	—	$ —	$ —
Granted	3,335,300	12.82	$ 42,759
Vested	—	—	$ —
Forfeited	—	—	$ —
Outstanding, December 31, 2021	3,335,300	$ 12.82	$ 42,759

Operational-Based Performance-Vesting RSUs

In September 2021 the Company issued 1,597,272 operational-based performance-vesting RSUs that vest based on the satisfaction of both a continued employment condition and the achievement of certain performance goals including meeting certain annual revenue targets and product development milestones.

The grant date fair value of operational-based performance-vesting RSUs was estimated based on their fair value of the Company's common stock on the date of grant. Compensation costs are recorded when achievement of the performance goals is determined to be probable. As of December 31, 2021 the revenue targets were met for 2021 and the revenue targets for 2022 were deemed to be probable. However, the product development milestone goals were not deemed to be probable and no compensation cost was recognized in 2021.

Operations-based performance-vesting RSU activity for the year ended December 31, 2021 are as follows:

	Underlying Shares	Weighted-average Grant Date Fair Value	Aggregate Fair Value
Outstanding, January 1, 2021	—	$ —	$ —
Granted	1,597,272	16.00	25,556
Vested	—	—	—
Forfeited	—	—	—
Outstanding, December 31, 2021	1,597,272	$ 16.00	$ 25,556

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 promissory notes to finance the entire cost of the shares. Due to the promissory notes being collateralized by the stock purchased and other stock held by the purchasers, these transactions were accounted for as substantive grants of common stock options since the purchasers did not assume the risk of ownership. Compensation expense was recognized ratably over a four-year service period. As of December 31, 2021, and 2020, there were 0 and 9,872,293 shares subject to the restricted stock purchase agreements, respectively.

In September 2021 the Company's board of directors approved the forgiveness of the Chief Executive Officer's 2018 and 2020 promissory notes under which $8.3 million of principal and accrued interest was outstanding for the purchase of 7,359,572 common stock shares. The Company's board of directors also approved the forgiveness of the Chief Product Officer's 2020 promissory notes under which $3.5 million of principal and accrued interest was outstanding for the purchase of 2,457,721 common stock shares.

The forgiveness of the promissory notes were deemed to be an option modification. The unrecognized grant date fair value and the incremental fair value from the modification resulting from the forgiveness of the promissory notes related to vested shares was recognized in stock-based compensation expense during the year ended December 31, 2021 and the unvested portion thereof will be recognized as stock-based compensation expense over the remaining vesting period. This

modification resulted in $12.9 million in additional stock-based compensation expense for the year ended December 31, 2021.

A summary of the Company's option activity related to common stock through restricted stock purchase agreements in exchange for Nonrecourse Notes during 2021 was as follows:

	Number of Shares
Outstanding, December 31, 2020	9,872,293
Forgiveness of promissory notes on vested shares of common stock	(9,872,293)
Outstanding, December 31, 2021	—

Early Exercise Liability

Unvested shares of early-exercised stock 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. 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 options during the year ended December 31, 2021:

	Number of Shares
Unvested at December 31, 2020	316,666
Vested	(316,666)
Unvested at December 31, 2021	—

As of December 31, 2021, there was no liability related to the early exercise of common stock options.

NOTE 13. 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, convertible notes, restricted stock and similar equity instruments granted by the Company. Some restricted stock units vest upon certain performance and market conditions and as they vest, the shares will be included in outstanding common shares. 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 considered 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, therefore, net losses for the years ended December 31, 2020 and 2019 was attributed entirely to common stockholders and there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

The following table reconciles net income and the weighted-average shares used in computing basic and diluted earnings per share:

	Year Ended December 31,		
	2021	2020	2019
Numerator:			
Net income (loss)	$ 86,418	$ (47,352)	$ (20,606)
Less: Income allocated to participating securities	53,310	—	—
Net income (loss) attributable to common stockholders – basic	33,108	(47,352)	(20,606)
Plus: Income allocated to non-participating securities	2,285	—	—
Net income (loss) attributable to common stockholders - diluted	$ 35,393	$ (47,352)	$ (20,606)
Denominator:			
Basic weighted-average common shares outstanding	52,815,449	16,315,730	15,760,246
Dilutive potential common stock issuable:			
Common stock warrants	81,517	—	—
Preferred stock warrants	37,074	—	—
Stock options	6,631,061	—	—
Restricted stock units	70,283	—	—
Diluted weighted-average shares outstanding	59,635,384	16,315,730	15,760,246
Net income (loss) attributable to common stockholders per share			
Basic	$ 0.63	$ (2.90)	$ (1.31)
Diluted	$ 0.59	$ (2.90)	$ (1.31)

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 calculations were as follows (in common stock equivalent shares):

	Year Ended December 31,		
	2021	2020	2019
Redeemable convertible preferred stock	—	83,526,065	54,527,458
Stock options	2,724,654	8,344,752	8,244,751
Early exercised stock options	—	316,666	—
Restricted stock units	5,624,195	—	—
Performance restricted stock units	4,932,572	—	—
Common stock subject to restricted stock purchase agreements	—	9,872,293	2,924,130
Common stock warrants	—	75,744	75,744
Redeemable convertible preferred stock warrants	—	79,882	79,882
Total	13,281,421	102,215,402	65,851,965

NOTE 14. INCOME TAXES

The Company’s effective income tax rate for the year ended December 31, 2021 was 27.5% compared to 0% in the corresponding period in the prior year. 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.

Components of income tax expense were as follows:

	Year Ended December 31,		
	2021	2020	2019
Current:			
U.S. federal	$ 9,483	$ —	$ —
State	19,808	—	—
Deferred:			
U.S. federal	3,468	—	—
State	—	—	—
Total income tax expense	$ 32,759	$ —	$ —

The effective tax rate of the provision for income taxes differs from the U.S. federal statutory rate as follows:

	2021	2020	2019
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
State and local income taxes, net of federal tax benefit	13.3 %	7.6 %	7.0 %
Permanent differences	(0.4)%	(1.3)%	(0.9)%
Change in valuation allowance	(18.6)%	(30.8)%	(30.9)%
Tax credits	(0.9)%	3.3 %	4.8 %
Non-deductible convertible note adjustments	11.0 %	— %	— %
Sec. 162(m) limitation	2.2 %	— %	— %
Uncertain tax position reserves	1.2 %	(0.7)%	(1.0)%
Stock-based compensation	(1.2)%	0.9 %	— %
Other	(0.1)%	— %	— %
Income tax expense	27.5 %	— %	— %

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 we are using to manage the underlying business.

The net change in total valuation allowance for the years ended December 31, 2021 and 2020 was a decrease of $20.2 million and an increase of $14.6 million, respectively. The $20.2 million net decrease in the valuation allowance during 2021 is primarily due to the recognition of federal tax benefits of $22.2 million in 2021 as a result of current operating activity, utilization of net operating loss carryforwards, and the availability of accelerated tax depreciation for United States federal tax purposes. The valuation allowance for U.S. state tax deferred tax assets increased by $2.0 million due to differences between the application of U.S. federal and state tax regulations for tax depreciation and limitations on the California net operating loss carryforwards. The $14.6 million net increase in 2020 was primarily due to the current period US federal and state net operating losses.

The significant components of deferred income taxes were as follows:

	2021	2020
Deferred tax assets:		
Net operating losses	$ 6,180	$ 29,217
Research and development credits	942	3,791
Operating lease liability	14,484	3,234
Share-based compensation	4,801	350
Accruals and reserves	5,740	3,189
Deferred revenue	24,976	—
State taxes	2,769	—
Gross deferred tax assets	59,892	39,781
Deferred tax liabilities:		
Operating right-of-use asset	21,471	2,376
Depreciation and amortization	28,207	3,511
Gross deferred tax liabilities	49,678	5,887
Gross deferred tax assets/(liabilities)	10,214	33,894
Valuation allowance	(13,682)	(33,894)
Net deferred tax asset/(liabilities)	$ (3,468)	$ —

At December 31, 2021, the Company has United States federal and state net operating loss ("NOL") carryforwards of $9.7 million and $60.6 million, respectively. The federal NOL carryforwards generated in pre-2018 tax years of $5.6 million will begin to expire in 2037 while Federal NOLs generated after 2017 of $4.1 million will carryforward indefinitely. The state NOL carryforwards of $60.6 million will begin to expire in 2031 unless previously utilized. At December 31, 2021, the Company also had federal research tax credit carryforwards of $1.2 million. The federal research tax credit carryforwards begin to expire in 2032, if not utilized.

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 an IRC Section 382/383 analysis. If a change in ownership were to occur, additional NOL and tax credit carryforwards could be subject to future limitations or expire unutilized. As of December 31, 2021, the Company has $9.7 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, 2021, the Company has $1.2 million of federal tax credit carryforwards subject to limitations related to the utilization under Section 383 of the Internal Revenue Code.

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.

	2021	2020	2019
Balance at January 1	$ 1,045	$ 705	$ 489
Decreases related to prior year tax positions, net	1,360	—	—
Increases related to current year tax positions	1,000	340	216
Balance at December 31	$ 3,405	$ 1,045	$ 705

As of December 31, 2021, the Company has approximately $3.4 million of unrecognized tax benefits of which $3.2 million would affect the Company's effective tax rate if recognized. As of December 31, 2021, 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 utilized as of December 31, 2021 for the 2011 and subsequent tax years.

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 was unable to offset current period taxable income with net operating losses. The Company continues to maintain its valuation allowance over California net operating losses. The Company will continue to evaluate the impact, if any, AB 85 may have on its financial statements and disclosures.

On December 27, 2020, the Consolidated Appropriations Act, 2021, (“CAA”) was signed into law in the United States. 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, 2021.

On March 11, 2021, the American Rescue Plan Act H.R. 1319 (“ARPA”) was 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 year ended December 31, 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 for a total of $20.0 million as documented in the CCTC Agreement. The Agreement covers tax years 2021-2025 and is awarded upon successful completion of milestones each year.

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 year ended December 31, 2021.

NOTE 15. 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, primarily related to a letter of credit with Comerica Bank as collateral required by one of the Company’s vendors. During the year ended December 31, 2021,

the Company entered into a Revolving Credit Agreement with a capacity of $130.0 million and all but one of the letters of credit were no longer required by the counterparties. The one letter of credit, totaling $6.0 million, has been 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 letter of credit in the amount of $6.0 million. The letter of credit was increased to $12.0 million in July 2021. In November 2021 East West Bank increased the letter of credit by $0.5 million. All other obligations under the Revolving Credit Agreement have otherwise been terminated. In November 2021, $0.8 million of cash was restricted in relation to a customs surety on international imports. The Company also has outstanding, letters of credit with Comerica Bank related to its real estate leases totaling $0.5 million as of December 31, 2021. All letters of credit are collateralized.

Legal Settlement

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. The amount was included in the statements of operations in general and administrative expenses for the year ended December 31, 2020. As of December 31, 2021, $4.5 million of this amount was included in accrued liabilities and other current liabilities in the balance sheets.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. In addition, they are designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, as appropriate to allow timely decisions regarding required disclosure. Pursuant to Rules 13(a)-13(e) and 15(d)-15(e) under the Exchange Act, our management, with the participation of our CEO and CFO, performed an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation and as a result our material weaknesses previously identified and further discussed below, the CEO and CFO concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of December 31, 2021.

Notwithstanding the identified material weakness, management believes the financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. generally accepted accounting principles.

Management's Report on Internal Control Over Financial Reporting

The Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Material Weaknesses

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. As previously reported, in connection with the audits of our 2019 and 2020 annual financial statements, we identified material weaknesses in internal controls pertaining to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) insufficient complement of qualified resources with an appropriate level of knowledge, v) experience and training important to our financial reporting requirements, vi) timely reconciliation and analysis of certain key accounts; and vii) the review of journal entries.

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 and a Chief Financial Officer in the first quarter of 2021, the hiring of a Vice President and Treasurer in the second quarter of 2021 and beginning in the fourth quarter of 2021 we added an Interim Controller, an Assistant Controller and a Director of Tax, and the continued engagement of additional external advisors to provide financial accounting assistance in the short term. As a result of the additional resources, we remediated the material weaknesses relating to insufficient complement of qualified resources with an appropriate level of knowledge, and timely reconciliation and analysis of certain key accounts.

As part of our ongoing efforts to remediate our material weaknesses during fiscal 2021, we also dedicated resources to capturing and documenting current state processes while identifying opportunities for process improvement. In addition, we continue to engage 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 have evaluated 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 material weaknesses. Although we have continued to enhance our internal controls over financial reporting during fiscal year 2021, in connection with the audit of our 2021 annual financial statements, management has concluded that the material weaknesses in internal controls pertaining to i) information technology general controls, ii) a lack of segregation of duties, iii) documentation and design of formalized processes and procedures, iv) experience and training important to our financial reporting requirements; and v) the review of journal entries cannot be considered remediated as of December 31, 2021. 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 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, 2021 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.

Change in Internal Control

Other than as described above, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections.

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters

The information required by this Item 12 of Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 of Form 10-K will be incorporated herein by reference in accordance with General Instruction G(3) to Form 10-K.

Part IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

1. Financial statements (see Part II, Item 8 of this report)

2. All financial statement schedules have been omitted because the information being called for is not required or the information required is included in the consolidated financial statements or the notes thereto

(b) The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

EXHIBIT INDEX

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-40824	3.1	September 28, 2021
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-40824	3.2	September 28, 2021
4.1	Specimen Stock Certificate evidencing the shares of common stock	S-1	333-259250	4.1	September 1, 2021
10.1+	2021 Stock Incentive Plan	S-1/A	333-259250	10.5	September 15, 2021
10.2+	Form of Stock Option Agreement under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.6	September 15, 2021
10.3+	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.7	September 15, 2021
10.4+	Form of Restricted Stock Unit Agreement for Participants (other than Non-Employee Directors) under the 2021 Stock Incentive Plan	S-1/A	333-259250	10.8	September 15, 2021
10.5+	2021 Employee Stock Purchase Plan	S-1/A	333-259250	10.9	September 15, 2021
10.6+	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors	S-1	333-259250	10.20	September 1, 2021
10.7+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Ayub Khattak	S-1	333-259250	10.21	September 1, 2021
10.8+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Clint Sever	S-1	333-259250	10.22	September 1, 2021
10.9+	Employment Agreement, dated July 8, 2021, by and between the Registrant and Chris Achar	S-1	333-259250	10.23	September 1, 2021
10.10+	Form of Restricted Stock Unit Agreement, by and between the Registrant and Ayub Khattak	S-1/A	333-259250	10.24	September 15, 2021
10.11+	Form of Restricted Stock Unit Agreement, by and between the Registrant and Clint Sever	S-1/A	333-259250	10.25	September 15, 2021
10.12+	Form of the Restricted Stock Agreement under 2014 Equity Incentive Plan between the Registrant and each of Rohan Oza and Robin Farias-Eisner	S-1/A	333-259250	10.26	September 15, 2021
23.1	Consent of BDO USA, LLP				
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				

32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101

+ Indicates management contract or compensatory plan

* Exhibit is furnished and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 16. Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cue Health Inc.

Date: March 29, 2022

By: /s/ Ayub Khattak
Ayub Khattak
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ John Gallagher
John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ayub Khattak Ayub Khattak	President, Chief Executive Officer, Director, Chairman of the Board (Principal Executive Officer)	March 29, 2022
/s/ John Gallagher John Gallagher	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2022
/s/ Joanne Bradford Joanne Bradford	Director	March 29, 2022
/s/ Chris Achar Chris Achar	Director	March 29, 2022
/s/ Xiangmin Cui Xiangmin Cui	Director	March 29, 2022
/s/ Carole Faig Carole Faig	Director	March 29, 2022
/s/ Maria Martinez Maria Martinez	Director	March 29, 2022
/s/ Scott Stanford Scott Stanford	Director	March 29, 2022

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Cue Health Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-259758) of Cue Health Inc. of our report dated March 29, 2022, relating to the financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP

San Diego, California
March 29, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ayub Khattak, certify that:

1. I have reviewed this report on Form 10-K of Cue Health Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ Ayub Khattak
Ayub Khattak
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Gallagher, certify that:

1. I have reviewed this report on Form 10-K of Cue Health Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ John Gallagher
John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K for the year ended December 31, 2021 of Cue Health Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies in his capacity as the specified officer of the Company, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

a. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

b. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 29, 2022

By: /s/ Ayub Khattak
Ayub Khattak
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2022

By: /s/ John Gallagher
John Gallagher
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Annual Report on Form 10-K to which it relates and shall not be deemed filed with the Securities and Exchange Commission or incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.