United States securities and exchange commission logo

May 19, 2021

Ayub Khattak
Chief Executive Officer
Cue Health Inc.
4980 Carroll Canyon Rd.
Suite 100
San Diego, CA 92121

Re: Cue Health Inc.
Draft Registration Statement on Form S-1
Submitted April 19, 2021
CIK No. 0001628945

Dear Mr. Khattak:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

General

1. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of those communications. Please contact the staff member associated with the review of this filing to discuss how to submit the materials, if any, to us for our review

Overview, page 1

2. We note that the disclosure throughout the Overview section appears overly anticipatory in nature versus the company's actual business and operations. In this regard, we note that you only have one approved product and that the majority of your diagnostic test kits remain subject to technical development and FDA approval. We also note that a

significant majority of your revenue is derived from two major customers. Please revise this section and the prospectus throughout to more accurately describe the current status of the company, its sole approved product and test kit, products and test kits in technical development and subject to FDA approval and the actual status and use of the company's platform and apps by active customers and users. We also note that the U.S. DoD agreement contains significant contractual obligations and restrictions which constrain your business and operations in the near-term. Please revise the Overview section to prominently discuss this agreement and any near-term constraints the agreement places on your business and operations.

3. We note that your platform, apps and sole approved product are relatively new. We also note your discussion throughout the prospectus regarding customers and users and their potential engagement via your platform and apps. Please disclose in an appropriate section the number of active customers and users on your platform and apps and how you define such terms.

4. We note that you have significant contractual obligations under the U.S. DoD agreement including certain production and delivery requirements. We also note that the U.S. government is entitled to all of your manufacturing output during the term of the agreement, subject to certain exceptions. Please revise the summary to highlight and discuss this agreement in greater detail as it appears to significantly affect your only approved product. In this regard, we note your risk factors on pages 21 and 22. Please also discuss your current shortfall with respect to the production target under the agreement, and the right of the U.S. government to terminate the agreement if you are unable to meet such targets.

Reinventing How We Interact with Our Health, page 1

5. Please refer to the fifth paragraph. We note your disclosure that your platform enables fast, frequent, lab-quality diagnostics by anyone, anywhere, facilitating a new continuous care model of personalized and contextualized healthcare. Please provide us with your basis for these statements. In this regard, we note that you only have one approved test kit and that your output and production is generally reserved for the U.S. DoD.

6. Please refer to the sixth paragraph and your discussion of your COVID-19 Test Kit. Please revise to clarify that your COVID-19 Test Kit is currently being marketed pursuant to EUAs and that it is your sole revenue generating product. Please also revise to balance the discussion by disclosing that you cannot predict how long the EUAs will remain in effect, and if they are terminated you will be required to stop selling the COVID-19 tests.

Please also discuss the steps necessary to receive FDA approval for the COVID-19 test through the standard regulatory pathway and the associated costs and timing, including whether you have started such process.

7. Please refer to the last paragraph on page 2. Please revise to

disclose your revenue and
net loss for 2019. In this regard, we note that you generated no product revenue in 2019
and reported a net loss. Additionally, please revise to clarify that two customers
accounted for 80% of your product revenue in 2020.

Our Expected Future Care Offerings, page 10

8. We note your disclosure that you have five tests in late-stage technical development and
that you anticipate submitting several tests to the FDA for authorization or clearance by
the end of 2022. Please clarify what you mean by "late-stage technical development" and
"several tests" and revise this section to discuss the five tests and their technical
development in greater detail. In this regard, for each of the five tests, please revise to
specifically identify the diagnostic test category, the stage of technical development,
regulatory filings or other requirements (i.e. the necessity of clinical studies, trials or FDA
510(k) or other clearance or approvals) and associated costs and timelines. Please
consider presenting this information in a pipeline table or other format so that investors
can easily appreciate the technical development of your various diagnostic test kits.

If the U.S. DoD terminates or fails to renew our agreement..., page 21

9. You state that if the DoD agreement is terminated for cause, you may be required to grant
the U.S. government a non-exclusive, paid up, perpetual license to the patents and
documentation necessary to develop the COVID-19 test. Please indicate whether your
inability to meet production targets would allow the U.S. government to terminate the
agreement for cause, and, if so, the impact on your current and future results of operations
if you were required to grant the U.S. government a license to the COVID-19 intellectual
property.

We currently rely upon the U.S. DoD and a very small number of other customers..., page 21

10. Please disclose the term of the DoD agreement so that investors understand the length of
time during which you are restricted from acquiring new customers. In this regard, we
note your disclosure on page F-15 that the agreement term ends upon final payment and is
anticipated to end in October 2021. Please clarify elsewhere as appropriate whether you
anticipate that the agreement will terminate in October 2021, and, if so, any material
impact due to such termination.

The COVID-19 pandemic could materially adversely affect our business, page 33

11. We note your disclosure that the COVID-19 pandemic delayed your clinical trial for your
influenza test. Please revise to discuss the nature of this delay in greater detail.

Clinical trials necessary to support a future test submission, page 61

12. Please revise this risk factor to clarify which diagnostic tests in your development pipeline
will require clinical studies or trials.

Use of Proceeds, page 82

13. We note your disclosure that you intend to use net proceeds to fund

research and
development and clinical studies to expand your test menu and to
continue to invest in
your technology applications and interfaces. Please revise to disclose
the net proceeds
intended to be used for each principal purpose individually.
Additionally, with respect to
net proceeds allocated to fund research and development and clinical
studies, please revise
to quantify the amounts allocated to fund the research and development
of each diagnostic
test kit individually and specify how far in the technical development
you expect to reach
with such net proceeds. If a material amount of other funds are
necessary to complete the
technical development of these diagnostic test kits, state the amounts
and sources of such
other funds. Refer to Instruction 3 of Item 504 of Regulation S-K.
Management's Discussion and Analysis of Financial Condition and Results of
Operations
Components of Our Results of Operations
Revenue, page 97

14. You disclose that your Cue Integrated Care Platform consists of
hardware and software
components and these components are designed to work together
seamlessly, creating an
easy-to-use workflow for your consumers. Please disclose your
accounting policy for
each component in your Cue Integrated Care Platform. In addition,
provide us your
accounting basis that supports your accounting referring to ASC 606
and other
authoritative literature, as applicable, specifically considering ASC
606-10-25-14 through
22.
Research and Development Expense, page 98

15. With regards to your research and development, you disclose that you
are developing tests
in the fields of respiratory health, sexual health, cardiac and
metabolic health, women's
health, men's health, and chronic disease management, with several of
these tests expected
to be submitted to the FDA for authorization or clearance by the end
of 2022. You further
note that you have five tests in late-stage technical development. As
such, please disclose
the costs incurred during each period presented for each of your key
research and
development projects. If you do not track your research and
development costs by
project, please disclose that fact and explain why you do not maintain
and evaluate
research and development costs by project. Provide other quantitative
or qualitative
disclosure that provides more transparency as to the type of research
and development
expenses incurred (i.e. by nature or type of expense) which should
reconcile to total
research and development expense on the Statements of Operations.

Healthcare 1.0, page 109

16. Please revise this section and the Healthcare 2.0 section throughout
to clarify that the
various statements, characterizations and conclusions of the current
healthcare system and
Healthcare 2.0 are the company's beliefs.
We are Positioned to Be at the Center of Healthcare 2.0, page 112

17. Please revise the first paragraph to balance the discussion by

clarifying that the company
currently only has one approved test kit pursuant to EUAs.
Our First Product Offering - Cue COVID-19 Test Kit, page 121

18. We note that your COVID-19 test kit has two EUAs. Please revise this section to discuss
the remaining steps necessary to receive FDA approval through the standard regulatory
pathway and the associated costs and timing.
Clinical Results, page 124

19. We note that the company completed a clinical study of its COVID-19 test kit. Please
revise to discuss the clinical study in greater detail. Please include enough details so that
investors can understand the specific details of the study to include dates, locations, study
purpose, endpoints and study results.
Future Care Offerings, page 130

20. For each diagnostic test described in this section, please revise to discuss in greater detail
the technical development of each test including the remaining stages of technical
development, regulatory filings or other requirements (i.e. the necessity of clinical studies,
trials or FDA 510(k) or other clearance or approvals) and associated costs and
timelines. To the extent clinical studies or trials will be required, please discuss these
requirements and any plans, costs and timelines to complete these studies or trials. Please
include enough details so investors can clearly appreciate where each test resides in your
development pipeline and the steps, costs and timelines necessary to obtain final FDA
approval. Please revise the Sexual Health, Chronic Disease Management and Women's
Health sections accordingly.
Sexual Health, page 132

21. We note that this section references a number of potential sexual health tests. However,
based on your disclosure, it appears that you have only began preliminary technical
development on a Chlamydia and Gonorrhea test kit. If true, please revise to clarify that
you have not completed any technical development on the other referenced sexual health
tests, i.e. HIV, Herpes and Hepatitis C. To the extent these sexual health tests are
aspirational in nature, please revise to clearly disclose that fact. Please revise the Chronic
Disease Management and Women's Health sections in a similar manner.

Principal Stockholders, page 181

22. Please revise to disclose the natural person or persons who have voting or investment
power with respect to the common stock held by the entities listed in the table.
Note 2, page F-8

23. Your accounting policy disclosures state that depreciation expense is allocated to R&D
and G&A which does not appear consistent with your disclosure on page F-17 that $3.2
million of your 2020 $6.2 million total depreciation and amortization expense was
alloacted to cost of product revenue. The $3m difference equals the depreciation and
amortization expense line item on your Statements of Operations suggesting that nothing
was allocated to the R&D and G&A expense line items. Please clarify the disclosures in
the filing.
Note 3, page F-15

24. Please provide us with more details concerning the $184.6 million advance you received from DoD to facilitate the scaling of the Company s manufacturing capacity.

Specifically, please fully describe any contractual restrictions on how you can use this advance and all circumstances under which you could be required to refund the advance.

Further, tell us whether there are any circumstances under which the DoD has a contractual right to take a security interest in any assets you acquire using the proceeds from the advance. Please clarify whether the advance impacts your cost basis in associated inventory and/or property and equipment costs. Also, please quantify the amount of payments you have received under this contract in 2021.

You may contact Sasha Parikh at 202-551-3627 or Al Pavot at 202-551-3738 if you have questions regarding comments on the financial statements and related matters. Please contact Donald Field at 202-551-3680 or Erin Jaskot at 202-551-3442 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences