

September 15, 2021

By Electronic Submission

U.S. Securities and Exchange Commission
Division of Corporation Finance
100 F Street, N.E.
Washington, DC 20549

Attention: Sasha Parikh

Re: **Cue Health Inc.**
Registration Statement on Form S-1
Filed September 1, 2021
File No. 333-259250

Ladies and Gentlemen:

Enclosed herewith, please find certain proposed revisions to the Company's Registration Statement (Registration Statement No. 333-259250) in response to the Staff's comment letter dated September 13, 2021, as shared with you yesterday via email. Please note that these proposed revisions are superseded by the revisions reflected in Amendment No. 1 to the Registration Statement filed today and discussed in our separate response letter dated today and relating thereto. If you have any questions regarding the enclosed material, please do not hesitate to call me at (212) 230-8837.

Very truly yours,

/s/ Glenn R. Pollner

Glenn R. Pollner

cc: Ayub Khattak, Cue Health Inc.
Erica Palsis, Cue Health Inc.
Charles S. Kim, Cooley LLP
Jonie Ing Kondracki, Cooley LLP
E. Thom Rumberger, Jr., Wilmer Cutler Pickering Hale and Dorr, LLP

RISK FACTORS

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

Risks Related to Our Business and Strategy

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

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

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

We have incurred significant losses since our inception in 2010, including net losses of \$20.6 million and \$47.4 million for the years ended December 31, 2019 and 2020, respectively. For the six months ended June 30, 2021, we had a net income of \$32.8 million. As of June 30, 2021, we had an accumulated deficit of \$77.6 million. While we were profitable for the first time in the first quarter of 2021, we cannot assure you that we will be able to continue to be profitable on an ongoing basis, either in the near term or longer term. We may continue to incur losses both in the near term and longer term as we continue to invest significant additional funds to scale up our business, including continuing to build out our commercial organization and corporate infrastructure, continuing to build out our manufacturing capabilities and engaging in continued research and development as we work to expand our menu of available tests and also as we incur additional costs associated with operating as a public company. Prior to August 2020, we had never generated any revenue from the commercial sale of products, and we had devoted substantially all of our resources to the research and development of our Cue Health Monitoring System. We only first started realizing revenue from commercial product sales in August 2020 following receipt of our first Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, in June 2020 for our COVID-19 test. Our COVID-19 test includes a Cue Reader and a COVID-19 Test Kit comprised of a Cue COVID-19 Cartridge and a Cue Wand. Since receiving our first FDA EUA, we have incurred significant additional expenses in connection with the commercial scale up of our business, including costs associated with scaling up our manufacturing operations, costs associated with the production of our COVID-19 test, sales and marketing expenses, and costs associated with the hiring of new employees, the growth of our business and building out our corporate infrastructure. In addition, we will incur significant additional expenses as we become a public company, further grow our business and continue to roll out our COVID-19 tests to the marketplace, pursue new customers and look to develop and commercialize new tests and other products for use with our Cue Integrated Care Platform. Therefore, our losses may continue to increase for at least the near term, if not longer. We are unable to predict whether or when we will become profitable on a sustained basis. Our ability to sustain profitability is based on numerous factors, many of which are beyond our control, including, among other factors, market acceptance of our products, the length of the COVID-19 pandemic, future product development, our market penetration and margins and our ability to expand our menu of tests. We may not be able to sustain or increase profitability in the future. Our inability to achieve and maintain profitability, whether in the near term or longer term, may make it difficult to continue to grow our business and accomplish our strategic objectives, and could materially adversely affect our business, financial condition, results of operations and future prospects.

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

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

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

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n.m. = not meaningful

Revenue increased by \$197.0 million to \$201.9 million in the six months ended June 30, 2021, from \$5.0 million in the six months ended June 30, 2020. This increase was due to the start of product sales in August 2020. Of the \$201.9 million of product revenue recorded in the six months ended June 30, 2021, \$159.7 million related to sales of our COVID-19 test and \$42.2 million was related to the amortization of the U.S. DoD Advance. Revenue increased by \$72.9 million in the three months ended June 30, 2021, to \$137.4 million, compared sequentially to \$64.5 million in the three months ended March 31, 2021. The increase of \$72.9 million was due to an increase of commercial customer sales of \$30.0 million (of which \$28.9 million was attributable to a single enterprise customer) and an increase in U.S. government revenue of \$42.9 million in the three months ended June 30, 2021 compared to the three months ended March 31, 2021. The increase in commercial customer revenue and subsequent decrease in U.S. government revenue in this period were driven by the U.S. DoD Waiver allowing us to increase sales to commercial customers beginning in May 2021.

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

Cost of Product Revenue increased by \$85.2 million in the six months ended June 30, 2021, from \$0 in the six months ended June 30, 2020. This increase was due to the fact that we did not incur cost of product revenue until we began to generate product revenue in August 2020 after receiving our first FDA EUA in June 2020. Product gross profit was \$116.7 million in the six months ended June 30, 2021, up from \$0 in the six months ended June 30, 2020, as we did not incur cost of product revenue prior to receipt of our first EUA. During the six months ended June 30, 2021, we identified certain immaterial amounts that were previously capitalized as intangible assets. These amounts were recorded as incremental amortization expense during the six months ended June 30, 2021 and recorded as cost of product revenue. Our cost of product revenue increased by \$25.1 million in the three months ended June 30, 2021 to \$55.1 million compared sequentially to \$30.0 million in the three months ended March 31, 2021. This increase of

\$25.1 million was due to increased production and sales volume to commercial customers resulting from the U.S. DoD Waiver in the three months ended June 30, 2021 compared to the three months ended March 31, 2021.

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

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

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

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

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

Income Tax Expense increased to \$13.3 million in the six months ended June 30, 2021 from \$0 in the six months ended June 30, 2020, and our effective tax rate was 29% in the six months ended June 30, 2021, compared to 0% in the six months ended June 30, 2020. The increase in our provision and effective tax rate was primarily due to the current tax liability arising from an increase in income from operations which exceeded available net operating loss carryforwards and the discrete impact of the fair value adjustment associated with the convertible notes that were issued in May 2021. Substantially all of our deferred tax assets continue to maintain a valuation allowance. Income tax expense increased \$10.8 million in the three months ended June 30, 2021, to \$12.0 million compared sequentially to \$1.2 million in the three months ended March 31, 2021. The increase of \$10.8 million was primarily due to the increase in net income during the period and an increase in forecasted revenue for the remainder of fiscal year 2021.

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

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

(1) Represents the tax impact with respect to the adjustments noted above. We applied an estimated annual effective tax rate of 24% to amounts deductible for tax purposes to estimate the tax effects.

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Liquidity and Capital Resources

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

As of June 30, 2021, we had an accumulated deficit of \$77.6 million, and cash, cash equivalents and restricted cash of \$252.3 million. Restricted cash included in such amount as of June 30, 2021 was \$6.0 million. For the six months ended June 30, 2021, we had net income of \$32.8 million and net cash used in operations of \$37.8 million. As of June 30, 2021, we had lease liabilities of \$52.5 million. In February 2021, we entered into a \$130.0 million loan and security agreement, or the Revolving Credit Agreement, with the lenders from time-to-time party thereto and East West Bank, as Administrative Agent and Collateral Agent for the lenders. Per the covenants of the Revolving Credit Agreement, we were required to maintain a balance of \$80.0 million on deposit with East West Bank. In May 2021, we raised \$229.5 million in net proceeds from the issuance and sale of Convertible Notes. In May 2021, we repaid \$63.2 million of debt outstanding under the Revolving Credit Agreement with a portion of the proceeds from the issuance and sale of the Convertible Notes. In June 2021, we terminated our Revolving Credit Agreement but kept in place our outstanding \$6.0 million letter of credit with East West Bank. In July 2021, we increased our outstanding letter of credit with East West Bank to \$12.0 million. In connection with such increase, our restricted cash increased to \$12.0 million as of such time.

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

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

We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, in

In response to SEC Comment #1 Risk Factors, Page 25

RIDER A

RISK FACTORS

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

We have incurred significant losses since our inception in 2010, including net losses of \$20.6 million and \$47.4 million for the years ended December 31, 2019 and 2020, respectively. For the six months ended June 30, 2021, we had a net income of \$32.8 million. As of June 30, 2021, we had an accumulated deficit of \$77.6 million. While we were profitable for the first time in the first quarter of 2021, we cannot assure you that we will be able to continue to be profitable on an ongoing basis, either in the near term or longer term. In connection with the completion of this offering, we expect to incur an incremental non-cash charge of \$38.7 million as a result of the automatic conversion of our Convertible Notes issued in May 2021. We estimated approximately \$62.0 million of discount on these notes that will be partially offset by the \$23.3 million of non-cash expense relating to the change in the fair value of the Convertible Notes that was recognized in our statements of operations for the six months ended June 30, 2021. If the offering closes after September 30, 2021, the total discount to be incurred in connection with the automatic conversion of the Convertible Notes upon completion of this offering would increase to \$78.5 million plus accrued interest at the time of closing. We also expect to recognize approximately \$14.9 million of non-cash stock-based compensation expense related to the forgiveness of certain promissory notes from our executives and the vesting of RSUs and option grants to executives and directors in connection with this offering. We expect to recognize this non-cash stock-based compensation expense in the period in which this offering is completed. As a result of these non-cash charges, we may have a net loss for the quarter ended September 30, 2021. We may continue to incur losses both in the near term and longer term as we continue to invest significant additional funds to scale up our business, including continuing to build out our commercial organization and corporate infrastructure, continuing to build out our manufacturing capabilities and engaging in continued research and development as we work to expand our menu of available tests and also as we incur additional costs associated with operating as a public company. Prior to August 2020, we had never generated any revenue from the commercial sale of products, and we had devoted substantially all of our resources to the research and development of our Cue Health Monitoring System. We only first started realizing revenue from commercial product sales in August 2020 following receipt of our first Emergency Use Authorization, or EUA, from the U.S. Food and Drug Administration, or FDA, in June 2020 for our COVID-19 test. Our COVID-19 test includes a Cue Reader and a COVID-19 Test Kit comprised of a Cue COVID-19 Cartridge and a Cue Wand. Since receiving our first FDA EUA, we have incurred significant additional expenses in connection with the commercial scale up of our business, including costs associated with scaling up our manufacturing operations, costs associated with the production of our COVID-19 test, sales and marketing expenses, and costs associated with the hiring of new employees, the growth of our business and building out our corporate infrastructure. In addition, we will incur significant additional expenses as we become a public company, further grow our business and continue to roll out our COVID-19 tests to the marketplace, pursue new customers and look to develop and commercialize new tests and other products for use with our Cue Integrated Care Platform. Therefore, our losses may continue to increase for at least the near term, if not longer. We are unable to predict whether or when we will become profitable on a sustained

basis. Our ability to sustain profitability is based on numerous factors, many of which are beyond our control, including, among other factors, market acceptance of our products, the length of the COVID-19 pandemic, future product development, our market penetration and margins and our ability to expand our menu of tests. We may not be able to sustain or increase profitability in the future. Our inability to achieve and maintain profitability, whether in the near term or longer term, may make it difficult to continue to grow our business and accomplish our strategic objectives, and could materially adversely affect our business, financial condition, results of operations and future prospects.

In response to SEC Comment #1 Risk Factors, Page 25

RIDER B

MANAGEMENT'S DISCUSSION AND ANALYSIS (Page 115)

Certain Expenses to be Incurred in Connection with Initial Public Offering

In connection with the completion of this offering, we expect to incur an incremental non-cash charge of \$38.7 million as a result of the automatic conversion of our Convertible Notes issued in May 2021. We estimated approximately \$62.0 million of discount on these notes that will be partially offset by the \$23.3 million of non-cash expense relating to the change in the fair value of the Convertible Notes that was recognized in our statements of operations for the six months ended June 30, 2021. If the offering closes after September 30, 2021, the total discount to be incurred in connection with the automatic conversion of the Convertible Notes upon completion of this offering would increase to \$78.5 million plus accrued interest at the time of closing. We also expect to recognize approximately \$14.9 million of non-cash stock-based compensation expense related to the forgiveness of certain promissory notes from our executives and the vesting of RSUs and option grants to executives and directors in connection with this offering. We expect to recognize this non-cash stock-based compensation expense in the period in which this offering is completed. As a result of these non-cash charges, we may have a net loss for the quarter ended September 30, 2021.

In response to SEC Comment #2 Cost of Product Revenue, Page 112

RIDER C

Our product gross margin as a percentage of total revenues increased to approximately 59.9% in the three months ended June 30, 2021 compared to approximately 53.4%, in the three months ended March 31, 2021. This increase was primarily due to higher absorption of fixed costs related to higher production volumes and efficiencies. DoD revenue pricing, inclusive of the DoD advance and related amortization recognized upon sale, was consistent quarter over quarter and the increase is directly related to the volume of products sold under the U.S. DoD Agreement.

In response to SEC Comment #3 Revenue, Page 111

RIDER D

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

In response to SEC Comment #4 Non-GAAP Financial Measures, Page 112

RIDER E

The fair value adjustment associated with our convertible notes and a portion of our banking and finance-related items were not deductible for income tax purposes and were excluded from the tax effects above.
