UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from to

Commission File Number: 001-39976

Lucira Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-2491037**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1412 62nd Street
Emeryville, California 94608
(Address of principal executive offices)

Registrant's telephone number, including area code: (510) 350-8071

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LHDX	Nasdaq Global Select Market

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, 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 10, 2021, the number of shares of registrant's common stock, par value $0.001 per share, outstanding was 38,698,789.

Table of Contents

Where You Can Find More Information

Investors and others should note that we announce material financial and other information using our investor relations website, press releases, SEC filings and public conference calls and webcasts. We also post supplemental materials on the Press Release section of our investor relations website at www. https://ir.lucirahealth.com/. Except as specifically noted herein, information on or accessible through our website is not, and will not be deemed to be, a part of this Quarterly Report on Form 10-Q or incorporated by reference into any other filings we may make with the U.S. Securities and Exchange Commission (the "SEC").

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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, which statements involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations or financial condition; business strategy and plans; and objectives of management for future operations, including our statements regarding the benefits and timing of the roll out of new technology, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these words or other similar terms or expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the extent and duration of the COVID-19 pandemic and our expectations regarding customer and user demand for our COVID-19 test kit;
- our expected future growth;
- our ability to obtain and maintain regulatory approval for our test kits, including our existing Emergency Use Authorizations, or EUAs, for our COVID-19 test kits;
- the size and growth potential of the markets for our test kits, including the COVID-19 diagnostic testing market, and our ability to serve those markets;
- our ability to accurately forecast demand for our test kits;
- the rate and degree of physician and market acceptance of our test kits;
- the expected future growth of our sales and marketing organization;
- coverage and reimbursement for our test kits;
- the performance of, and our reliance on, third parties in connection with the commercialization of our test kits, including Jabil Inc., or Jabil, and our single-source suppliers;
- our ability to accurately forecast, and Jabil’s ability to manufacture, appropriate quantities of our COVID-19 test kit to meet commercial demand;
- regulatory developments in the United States and foreign countries;
- our research and development for our influenza test kit and any future test kits;
- the development, regulatory approval, and commercialization of competing products;
- our ability to retain and hire senior management and key personnel;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our financial performance and capital requirements; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our test kits, as well as our ability to operate our business without infringing the intellectual property rights of others.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. The results, events, and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe that such information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q 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.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

“Lucira Health,” “Lucira,” the Lucira Health logo and our other registered or common law trade names, trademarks or service marks appearing in this Quarterly Report on Form 10-Q are our property. Trade names, trademarks and service marks of other companies appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, the trademarks and tradenames referred to in this Quarterly Report on Form 10-Q appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

LUCIRA HEALTH, INC.
CONDENSED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	June 30, 2021	December 31, 2020 (1)
Assets		
Current assets:		
Cash	$ 161,662	$ 58,212
Accounts receivable, net	3,392	293
Inventory	36,182	4,865
Grant income receivable	92	183
Prepaid expenses	6,164	3,496
Other current assets	6,099	844
Restricted cash equivalents	2,338	2,338
Total current assets	215,929	70,231
Property and equipment, net	28,153	19,408
Operating lease right-of-use assets	576	748
Other assets	31	2,316
Total assets	$ 244,689	$ 92,703
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,673	$ 3,981
Accrued liabilities	18,672	4,445
Operating lease liabilities, current	374	431
Customer deposits	2,916	—
Total current liabilities	28,635	8,857
Convertible notes payable	—	24,694
Operating lease liabilities, net of current portion	254	380
Total liabilities	28,889	33,931
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock $0.001 par value; 0 and 103,355,827 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 0 and 23,978,747 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively; aggregate liquidation preference of $0 as of June 30, 2021	—	121,080
Stockholders' equity (deficit):		
Preferred stock $0.001 par value; 10,000,000 and 0 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 0 shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 200,000,000 and 150,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 38,684,546 and 2,712,694 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	39	3
Additional paid-in capital	308,991	1,403
Accumulated deficit	(93,230)	(63,714)
Total stockholders' equity (deficit)	215,800	(62,308)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 244,689	$ 92,703

(1) The balance sheet as of December 31, 2020 is derived from the audited financial statements as of that date

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

LUCIRA HEALTH, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net sales	$ 12,439	$ —	$ 16,955	$ —
Cost of products sold	12,505	—	17,873	—
Gross loss	(66)	—	(918)	—
Operating expenses:				
Research and development	10,117	4,574	16,399	7,315
Selling, general and administrative	6,100	931	12,200	1,559
Total operating expenses	16,217	5,505	28,599	8,874
Loss from operations	(16,283)	(5,505)	(29,517)	(8,874)
Other income (expense), net:				
Grant income	79	335	281	1,977
Interest income (expense)	4	(10)	1	(10)
Remeasurement of derivative liabilities and convertible notes	—	(1,444)	(281)	(1,444)
Total other income (expense), net	83	(1,119)	1	523
Net loss	$ (16,200)	$ (6,624)	$ (29,516)	$ (8,351)
Net loss per share of common stock, basic and diluted	$ (0.42)	$ (2.90)	$ (0.96)	$ (3.68)
Weighted-average number of shares used in net loss per share of common stock, basic and diluted	38,483,766	2,282,024	30,688,349	2,270,130

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

LUCIRA HEALTH, INC.
CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance as of March 31, 2021	-	-	38,550,148	39	307,903	$ (77,030)	$ 230,912
Issuance of common stock upon exercise of stock options	-	-	134,398	-	143	-	143
Stock-based compensation	-	-	-	-	945	-	945
Net loss	-	-	-	-	-	(16,200)	(16,200)
Balance as of June 30, 2021	-	$ -	38,684,546	$ 39	$ 308,991	$ (93,230)	$ 215,800

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of March 31, 2020	10,466,169	$ 48,426	2,257,740	$ 2	$ 757	$ (28,093)	$ (27,334)
Issuance of common stock upon exercise of stock options	-	-	187,164	-	153	-	153
Stock-based compensation	-	-	-	-	59	-	59
Net loss	-	-	-	-	-	(6,624)	(6,624)
Balance as of June 30, 2020	10,466,169	$ 48,426	2,444,904	$ 2	$ 969	$ (34,717)	$ (33,746)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2020	23,978,747	$ 121,080	2,712,694	3	1,403	$ (63,714)	$ (62,308)
Conversion of redeemable convertible preferred shares into common stock	(23,978,747)	(121,080)	23,978,747	24	121,056	-	121,080
Conversion of convertible notes into common stock	-	-	1,470,947	2	24,980	-	24,982
Issuance of common stock upon IPO, net of issuance costs	-	-	10,350,000	10	159,889	-	159,899
Issuance of common stock upon exercise of stock options	-	-	172,158	-	190	-	190
Stock-based compensation	-	-	-	-	1,473	-	1,473
Net loss	-	-	-	-	-	(29,516)	(29,516)
Balance as of June 30, 2021	-	$ -	38,684,546	$ 39	$ 308,991	$ (93,230)	$ 215,800

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of December 31, 2019	6,712,085	$ 30,960	2,257,740	$ 2	$ 699	$ (26,366)	$ (25,665)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs	3,754,084	17,466	-	-	-	-	-
Issuance of common stock upon exercise of stock options	-	-	187,164	-	153	-	153
Stock-based compensation	-	-	-	-	117	-	117
Net loss	-	-	-	-	-	(8,351)	(8,351)
Balance as of June 30, 2020	10,466,169	$ 48,426	2,444,904	$ 2	$ 969	$ (34,717)	$ (33,746)

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

LUCIRA HEALTH, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (29,516)	$ (8,351)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,473	117
Allowance for doubtful accounts	259	
Depreciation and amortization	882	118
Remeasurement of derivative liabilities and convertible notes	281	1,444
Noncash interest expense	3	6
Noncash lease expense	172	150
Changes in assets and liabilities:		
Inventory	(31,317)	—
Accounts receivable	(3,358)	—
Grant income receivable	91	1,639
Prepaid expenses and other current assets	(8,767)	(800)
Other assets	3,129	—
Accounts payable	2,678	527
Customer deposits	2,916	—
Accrued liabilities	13,635	47
Operating lease liabilities	(183)	(135)
Net cash used in operating activities	(47,622)	(5,238)
Cash flows from investing activities:		
Acquisition of property and equipment	(8,977)	(2,285)
Net cash used in investing activities	(8,977)	(2,285)
Cash flows from financing activities:		
Proceeds from issuance of common stock on IPO, net of issuance costs	159,899	—
Proceeds from issuance of convertible notes payable net of issuance costs	—	5,612
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	17,466
Proceeds from exercise of stock options	150	153
Net cash provided by financing activities	160,049	23,231
Net increase in cash and restricted cash equivalents	103,450	15,708
Cash and restricted cash equivalents, beginning of period	60,550	4,100
Cash and restricted cash equivalents, end of period	164,000	19,808
Reconciliation to amounts on the balance sheets:		
Cash	$ 161,662	$ 19,808
Restricted cash equivalents	2,338	—
Total cash and restricted cash equivalents	$ 164,000	$ 19,808
Supplemental disclosures of noncash financing and investing activities:		
Purchase of property and equipment included in accounts payable and accrued liabilities	$ 650	$ —
Vesting of early exercise options	$ 40	$ —
Conversion of redeemable convertible notes payable principal and interest for common stock on IPO	$ 24,982	$ —
Conversion of convertible redeemable preferred shares into common stock on IPO	$ 121,080	$ —

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

Note 1. Organization

Description of Business

Lucira Health, Inc. (the "Company") was incorporated under the laws of the state of Delaware on February 20, 2013 under the name DiAssess Inc. The Company changed its name to Lucira Health, Inc. in January 2020. The Company is located in Emeryville, California.

The Company is a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits. The Company has developed a testing platform that produces high-complexity-laboratory-accurate molecular testing in a single-use and user-friendly test kit that is powered by two AA batteries and fit in the palm of a hand. The Company's initial focus is within respiratory diseases, and initially for COVID-19 and influenza Types A and B indications.

On November 17, 2020, the Company received an Emergency Use Authorization ("EUA") from the Food and Drug Administration ("FDA") for (1) prescription at-home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider and (2) use at the point-of-care ("POC"), with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC. People who are suspected of COVID-19 are those who are either symptomatic or are thought to have been exposed to COVID-19. On April 9, 2021, the Company received its first FDA EUA authorization for over-the-counter ("OTC") non-prescription use among symptomatic and asymptomatic individuals aged 14 and older (with self-collection) and children aged two to 13 (with parent collection).

Reverse Stock Split

On January 28, 2021, the Company's board of directors (the "Board") approved a 1-for-4.3103 reverse stock split (the "Reverse Stock Split") of the Company's common stock and each series of its redeemable convertible preferred stock to be consummated prior to the effectiveness of the Company's initial public offering ("IPO") on February 4, 2021. The par value and authorized shares of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, preferred stock, options to purchase common stock and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented. The Company filed an amended and restated certificate of incorporation with the Secretary of State of the State of Delaware on January 28, 2021 that automatically effectuated the Reverse Stock Split without any further action required.

Initial Public Offering

On February 9, 2021, the Company closed its IPO of 10,350,000 shares of its common stock, including 1,350,000 shares of common stock issued pursuant to the full exercise of the underwriters' option to purchase additional shares in the IPO, at a price to the public of $17.00 per share. The net proceeds to the Company from the IPO were $159.9 million, after deducting underwriting discounts and commissions of $12.3 million and offering expenses of $3.7 million. In connection with the IPO, all shares of redeemable convertible preferred stock and outstanding convertible notes converted into 25,449,694 shares of common stock.

Liquidity and Going Concern

The Company has incurred recurring losses and negative cash flows from operating activities since inception. The Company anticipates that it will continue to incur net losses into the foreseeable future. As of June 30, 2021, the Company had cash of $161.7 million and had an accumulated deficit of $93.2 million. The Company believes that cash as of June 30, 2021 will be sufficient to fund its planned operations for a period of at least 12 months from the date of the issuance of the accompanying financial statements.

Management expects to incur additional losses in the future and in order to continue to fund its operations the Company may need to raise additional capital to fully implement its business plan. The Company may raise additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of new test kits.

Other Risk and Uncertainties

While the Company generated $17.0 million of revenues from the sale of its test kits during the six months ended June 30, 2021, there still remains uncertainty of future revenue from sales of its test kits. The Company is devoting most of its efforts to the sales and marketing and research and development of its test kits. The Company is subject to a number of product risks, including the receipt of regulatory approvals for additional indications of the COVID-19 test kit and timing thereof, size of the market opportunity, demand from the public and members of the medical community for the COVID-19 test kit and rate of adoption of the COVID-19 test kit. The commercial success of the COVID-19 test kit was initially dependent upon physicians, and healthcare providers accepting and adopting our test kit. Since receiving the EUA authorization for OTC use, our commercial business has evolved to include partnerships with testing providers, distributors and businesses. The Company is also subject to risks related to compliance with government regulations, protection of proprietary technology, dependence on third-parties, product liability, and dependence on key individuals.

In connection with the COVID-19 pandemic, governments have implemented significant measures, including closures, quarantines, travel restrictions and other social distancing directives, intended to control the spread of the virus. Companies have also taken precautions, such as requiring employees to work remotely, imposing travel restrictions and temporarily closing businesses. The Company believes some of the precautionary measures and challenges resulting from the COVID-19 pandemic may continue as COVID-19 becomes endemic, but there is uncertainty and volatility in these and other trends despite the continued progress of vaccination efforts. To the extent that restrictions remain in place, additional prevention and mitigation measures are implemented in the future, or there is uncertainty about the effectiveness of these or any other measures to contain or treat COVID-19, there is likely to be an adverse impact on global economic conditions and consumer confidence and spending, which could materially and adversely affect the Company's research and development, as well as operational activities. At this time, the Company is working to manage and mitigate potential disruptions to its research and future manufacturing and supply chain considerations. The Company has not experienced hindrance to its operations or material negative financial impacts as compared to prior periods. At this time, the extent to which the COVID-19 pandemic impacts the Company's business will depend on future developments, which are highly uncertain and cannot be predicted.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"), and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information and pursuant to the instructions of the SEC on Form 10-Q and Article 10 of Regulation S-X of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the management's opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

The accompanying balance sheet as of June 30, 2021, the statements of operations for the three and six months ended June 30, 2021 and June 30, 2020, the statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the three and six months ended June 30, 2021 and June 30, 2020, and the statements of cash flows for the six months ended June 30, 2021 and 2020 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2021 and the results of its operations and cash flows for the six months ended June 30, 2021 and June 30, 2020. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2021 and June 30, 2020 are unaudited. The results for the three and six months ended June 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. These financial statements and accompanying notes should be read in conjunction with the financial statements and notes thereto in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC on March 31, 2021.

Use of Estimates

Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to recognition of grant income, the fair value of the Company's common stock and redeemable convertible preferred stock, the fair value of derivative liabilities and convertible notes payable, stock-based compensation, incremental borrowing rate, revenue recognition, inventory valuation, sales returns, warranty reserves, allowance for doubtful accounts, accrued research and development costs, uncertain tax positions, the recoverability of its long-lived assets and the valuation of deferred tax assets. 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.

Concentration of Credit Risk and Significant Suppliers

Financial instruments that potentially subject the Company to credit risk consist principally of cash held by financial institutions, grant income receivables and account receivables. Substantially all of the Company's cash is held at one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits.

The Company's grant income receivable balance at each respective balance sheet dates results from grant agreements with the U.S. government.

As of June 30, 2021, accounts receivable balance was $3.4 million. Two customers accounted for 12% and 10% of accounts receivable balance. As of December 31, 2020, accounts receivable balance was $0.3 million and was comprised by the Company's only customer. The Company evaluates the collectability of its accounts receivable based on historical collection trends and provides for an allowance for doubtful accounts. Allowance for doubtful accounts was $0.4 million and $0 million as of June 30, 2021 and December 31, 2020, respectively. Two customers accounted for 14% and 10% of the Company's revenue during the three and six months ended June 30, 2021.

The Company is dependent on key suppliers, who are single source, for certain laboratory materials and inventory items. An interruption in the supply of these materials could temporarily impact the Company's ability to manufacture its commercial inventory and perform development, testing and clinical trials related to its products.

Fair Value Measurements

The carrying value of the Company's cash, accounts receivable, grant income receivable, prepaid expenses, other current assets and accrued liabilities approximate fair value due to the short-term nature of these items.

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; and
- 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 derivative liabilities and convertible notes are measured at fair value on a recurring basis and are classified as Level 3 liabilities until conversion of the notes. The Company records subsequent adjustments to reflect the increase or decrease in estimated fair value at each reporting date on the statement of operations.

Cash, and Restricted Cash Equivalents

The Company considers highly liquid investments purchased with a remaining maturity date upon acquisition of three months or less to be cash equivalents and are stated at cost, which approximates fair value. As of June 30, 2021 and June 30, 2020, there were no cash equivalents.

As of June 30, 2021, the Company held a restricted cash balance of $2.3 million which was used to secure a letter of credit in relation to the Company's contract manufacturer to secure certain purchases made on the Company's behalf. The cash was deposited in a money market account with maturities of three months or less and thus considered a restricted cash equivalent.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when positive results have been obtained for the clinical trials that the Company determines are necessary to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and the Company has determined it is probable that these capitalized costs will provide future economic benefit in excess of capitalized costs. The factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive clinical test results for the underlying product, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and the submission of the regulatory application. The Company closely monitors the status of each respective product within the regulatory approval process, including all relevant communication with regulatory authorities. If the Company is aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized.

For inventories that are capitalized in preparation of product launch, anticipated future sales, expected approval date and shelf lives are evaluated in assessing realizability. The shelf life of a product is determined as part of the regulatory approval process; however, in evaluating whether to capitalize pre-launch inventory production costs, the Company considers the product stability data of all of the pre-approval production to date to determine whether there is adequate expected shelf life for the capitalized pre-launch production costs. Prior to obtaining the EUA authorization for its COVID-19 test kit on November 17, 2020, the Company charged $2.3 million of preapproval inventory to research and development expense. After receipt of the EUA in November 2020, the Company accounted for all production item purchases as inventory in accordance with its inventories policy below. Preapproval inventories previously recorded as research and development expense that are subsequently sold will have a zero cost of product. Subsequent to receipt of the EUA in November 2020, the Company utilized a portion of the preapproval inventory resulting in a remaining unused amount of $1.3 million as of December 31, 2020. During the three months ended June 30, 2021, the Company utilized less than $0.1 million of the preapproval inventory write-offs for cost of sales. During the six months ended June 30, 2021, the Company utilized all of the preapproval inventory write-offs for cost of sales of $1.0 million and for selling, general and administrative and research and development activities of $0.3 million.

Inventories

The Company values its inventory at the lower of cost or net realizable value and determines the cost of inventory using standard costs which closely resembles the first-in, first-out method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The Company periodically reviews its inventories for shelf life, excess or obsolescence and writes-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. If the actual net realizable value is less than that estimated by the Company, or if it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required. Amounts written-down due to unmarketable inventory are recorded in cost of revenue and a new lower-cost basis for the inventory is established. The Company did not record any write down adjustment during the six months ended June 30, 2021.

Warranty

The Company offers a standard product warranty that our products will perform as intended upon the date of original delivery for a reasonable period of time, which is the shorter of date usage or product shelf life. The Company has the obligation, at its option, to either refund, repair or replace a defective product. At the time revenue is recognized, an estimate of future warranty costs is recorded as a component of cost of products sold. The estimate of future warranty costs is based on historical as well as current product failure rates, service delivery costs incurred in correcting product failures, and warranty policies. The Company will regularly review these estimates to assess the appropriateness of our recorded warranty liabilities and adjust the amounts as necessary. As of June 30, 2021 and December 31, 2020, the accrued liability for warranty returns was not significant.

Grant Income Receivable

Grant income receivable consists of billed and unbilled amounts earned from various government grants for costs incurred prior to the period end under reimbursement contracts. The amounts are billed to the respective government agencies. As collection is deemed probable, no allowance for doubtful accounts has been established. If amounts become uncollectible, they are recorded as operating expense in the Company's statements of operations. Of the amounts presented on the balance sheets as grant income receivable, $0.1 million and $0.2 million were unbilled as of June 30, 2021 and December 31, 2020, respectively.

Property and Equipment, Net

Property and equipment are stated at cost, net of depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and seven years. Leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful life of the asset or the remaining term of the related lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in other income or expense in the statements of operations in the period realized.

Leases

The Company determines if an arrangement is a lease at inception and if so, determines whether the lease qualifies as operating or finance. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the balance sheets. The Company did not have any finance leases as of June 30, 2021 and December 31, 2020.

ROU 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. Operating lease ROU 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 Company uses the implicit rate when readily determinable. The operating lease ROU assets also include any lease payments made and exclude lease incentives when paid by the Company or on the Company's behalf. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components. The Company elected to not separate lease and non-lease components for all of its building leases. The Company also made an accounting policy election to recognize lease expense for leases with a term of 12 months or less on a straight-line basis over the lease term and not recognize ROU assets or lease liabilities for such leases.

Long-Lived Assets

The Company's long-lived assets are comprised principally of its property and equipment, including leasehold improvements and ROU assets.

If the Company identifies a change in the circumstances related to its long-lived assets that indicates the carrying value of any such asset may not be recoverable, the Company will perform an impairment analysis. A long-lived asset is deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. No impairment of long-lived assets was recorded during the six months ended June 30, 2021 and June 30, 2020.

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. The Company records the estimated costs of research and development activities based upon 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. The Company records accrued expenses for these costs based on factors such as estimates of the work completed or supplies received and in accordance with agreements established with these vendors. 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. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, the Company adjusts its accrued estimates.

Redeemable Convertible Preferred Stock

The Company's shares of preferred stock are assessed at issuance for classification and redemption features requiring bifurcation. The Company's preferred stock is not mandatorily redeemable. The Company presents as temporary equity any stock which (i) the Company undertakes to redeem at a fixed or determinable price on the fixed or determinable date or dates; (ii) is redeemable at the option of the holders, or (iii) has conditions for redemption which are not solely within the control of the Company. The Company's preferred stock is redeemable if the Company has not been dissolved within 90 days following the occurrence of certain deemed liquidation events, which the Company determined is not solely within its control and thus has classified shares of redeemable convertible preferred stock as temporary equity until such time as the conditions are removed or lapse. The Company initially records redeemable convertible preferred stock at fair value, net of issuance costs. Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the shares of redeemable convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the shares of redeemable convertible preferred stock would be made only when a deemed liquidation event becomes probable.

In connection with the IPO on February 9, 2021, all outstanding shares of redeemable convertible preferred stock converted into 23,978,747 shares of common stock.

Deferred Offering Costs

The Company capitalized certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings, including the IPO, as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the equity financing. If a planned equity financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the condensed statements of operations. There was $0.0 and $2.2 million of deferred offering costs related to the Company's IPO recorded as other assets on the Company's balance sheet as of June 30, 2021 and December 31, 2020, respectively. The Company recorded additional offering costs between December 31, 2020 and February 9, 2021 and recorded $3.7 million as an offset to the IPO proceeds as additional paid in capital on the closing date.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification ("ASC") Topic 606 ("ASC 606"), "Revenue from Contracts with Customers" when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;
(ii) identify the performance obligations in the contract;
(iii) determine the transaction price;
(iv) allocate the transaction price to the performance obligations in the contract; and
(v) recognize revenue when (or as) the entity satisfies a performance obligation.

Under ASC 606, assuming all other revenue recognition criteria have been met, the Company will recognize revenue for arrangements upon the transfer of control of the Company's products to its customers, which is currently upon the shipment of the product to the customer under the Company's standard terms and conditions. There are no further performance obligations by the Company to the customer after shipment of the product. Control of the Company's products is transferred at a point in time.

Revenue is measured based on the amount of consideration that the Company expects to receive as reduced by estimated discounts and allowances.

All of the Company's revenue has been derived from sales of its test kits. During the first quarter 2021 the Company marketed its test products to physicians and licensed healthcare providers in the United States. On April 9, 2021, the Company received its first FDA EUA authorization for OTC non-prescription use and expanded its marketing to include domestic testing providers, distributors, businesses and international distributors.

Collection of the Company's net receivables generally occur within 30 days of billing. Contracts do not contain significant financing components based on the typical period of time between delivery of products and collection of consideration.

Costs to obtain or fulfill a contract are currently expensed when incurred because our performance obligation is satisfied at a point in time.

The Company invoices its customers upon shipment of product, and records its sales upon shipment in accordance with its standard terms and conditions, unless underlying customer contracts specify otherwise.

When necessary, the Company invoices and collects sales tax from its customers for sales of products. The Company has elected to exclude sales tax from the measurement of the transaction price.

The following table sets forth the Company's revenue by geographic area based on the customers' locations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
United States	$ 10,277	$ —	$ 14,793	$ —
International	2,162	—	2,162	—
Total revenue	$ 12,439	$ —	$ 16,955	$ —

Grant Income

The Company earns grant income for performing tasks under research and development agreements with governmental agencies.

In July 2018, the Company entered into an agreement with the Biomedical Advanced Research and Development Authority ("BARDA"), a division within the U.S. Department of Health and Human Services ("HHS"), for an award of up to $10 million to demonstrate the feasibility of a novel in-home, disposable, point-of-care rapid diagnostic assay for the detection of Influenza A and B for work performed through July 2020. In September 2019, the Company amended its agreement with BARDA to increase the award to $21.5 million and extend the reporting period through July 2022. The Company recognized grant income from BARDA of $0.0 for the three and six months ended June 30, 2021, compared to $0.4 million and $2.0 million for the three and six months ended June 30, 2020, respectively.

The Company recognized grant income from other governmental agencies of $0.1 million and $0.3 million during the three and six months ended June 30, 2021, respectively, compared to less than $0.1 million and $0.1 million during the three and six months ended June 30,2020, respectively.

Grant income derived from reimbursement of direct out-of-pocket expenses, overhead allocations and fringe benefits for research costs associated with government contracts and grants are recorded at the gross amount within grant income. The costs associated with these reimbursements are reflected as a component of research and development expense in the Company's statements of operations.

Research and Development

Costs associated with research and development activities are expensed as incurred and include, but are not limited to, personnel-related expenses including stock-based compensation expense, materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies and allocated overhead including rent and utilities.

Advertising and Marketing Costs

Costs associated with advertising and marketing activities are expensed as incurred. Total advertising and marketing costs were $0.9 million and $1.3 million for the three and six months ended June 30, 2021, respectively compared to $0 million in 2020, and are included in selling, general and administrative expenses in the accompanying statements of operations.

Stock-Based Compensation

The Company's stock-based awards consist of stock options, restricted stock awards, and employee stock purchase plan issued to grantees. The Company measures the estimated fair value of the stock-based awards on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective awards. The Company records expense for awards with service-based vesting using the straight-line method. The Company accounts for forfeitures as they occur.

In January 2021, the Company's Board adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The stockholders approved the 2021 Plan in January 2021, and it became effective upon the execution of the underwriting agreement for the IPO on February 4, 2021. Under the 2021 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock or cash-based awards to individuals who are then employees, officers, directors or consultants of the Company. No further grants will be made under the 2014 Equity Incentive Plan.

In February 2021, the Board adopted the 2021 Employee Stock Purchase Plan (the "ESPP"). The Company recognizes stock-based compensation expense related to shares issued pursuant to its ESPP on a straight-line basis over the offering period, which is generally six months. The ESPP allows employees to purchase shares of the Company's common stock at a 15 percent discount. The ESPP also includes a six-month look-back provision for the purchase price if the stock price on the purchase date is less than the stock price on the offering.

The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's cash compensation costs are classified.

The fair value of each restricted stock award is determined based on the number of shares granted and the value of the Company's common stock on the date of grant.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes option-pricing model requires the use of a number of complex assumptions including the fair value of the common stock, expected volatility, risk-free interest rate, expected dividends, and expected term of the option. Prior to the Company's initial public offering, the Company was a private company and lacked company-specific historical and implied fair value information. Therefore, the Board considered numerous objective and subjective factors to determine the fair value of the Company's common stock options at each meeting in which awards were approved. The factors considered include, but are not limited to (i) the results of contemporaneous independent third-party valuations of the Company's common stock and the prices, rights, preferences and privileges of the Company's redeemable convertible preferred stock relative to those of its common stock; (ii) the lack of marketability of the Company's common stock; (iii) actual operating and financial results;(iv) current business conditions and projections; (v) the likelihood of achieving a liquidity event, such as an IPO or sale of the Company, given prevailing market conditions, and (vi) precedent transactions involving the Company's shares.

The Company determined the expected stock volatility using a weighted-average of the historical volatility of a group of guideline companies that issued options with substantially similar terms, and expects to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the simplified method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess

of their net recorded amount, management would adjust the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (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. 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.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock equivalents of potentially diluted securities outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of redeemable convertible preferred stock, and options outstanding under the Company's stock option plan. For the six months ended June 30, 2021 and June 30, 2020, there was no difference in the number of shares used to calculate basic and diluted shares outstanding as the inclusion of the potentially dilutive securities would be anti-dilutive.

The following table summarizes the Company's net loss per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator				
Net loss attributable to common stockholders basic and diluted	$ (16,200)	$ (6,624)	$ (29,516)	$ (8,351)
Denominator				
Weighted-average number of common shares outstanding, basic and diluted	38,483,766	2,282,024	30,688,349	2,270,130
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (2.90)	$ (0.96)	$ (3.68)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	As of June 30,	
	2021	2020
Redeemable convertible preferred stock	-	10,466,169
Options to purchase common stock	5,107,453	2,475,455
Unvested restricted stock	1,097,935	—

Segment Reporting

The Company has determined that the Chief Executive Officer is its Chief Operating Decision Maker. The Company's Chief Executive Officer reviews financial information presented on an aggregate basis for the purposes of assessing the performance and making decisions on how to allocate resources. Accordingly, the Company has determined that it operates in a single operating and reportable segment, which is the business of designing, manufacturing and selling of disposable test kits.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements, or Accounting Standard Updates ("ASU") are issued by the Financial Accounting Standards Board ("FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

The Company is an emerging growth company ("EGC") as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. This means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company has the option to adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company has elected to use the extended transition period for complying with new or revised accounting standards unless the Company otherwise early adopts select standards.

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The guidance removes specific exceptions to the general principles in Topic 740, improves application of income tax-related guidance and reduces complexity related to the accounting for income taxes. The standard is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within that year. Early adoption is permitted. Entities that elect to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes the interim period. Additionally, entities that elect early adoption must adopt all the amendments in the same period. Entities will apply the guidance prospectively, except for certain amendments. The Company early adopted ASU 2019-12 effective January 1, 2021. The adoption of this standard did not have a material impact on the Company's financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The standard is effective for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company expects to adopt this ASU beginning January 1, 2023. The Company is evaluating the potential impact of this standard on its financial statements.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40):Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.* This update provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. This update is effective for fiscal years beginning after December 15, 2021. The Company is evaluating the potential impact of this standard on its financial statements.

Note 3. Fair Value Measurements

The Company's restricted cash equivalent is measured at fair value on recurring basis as of June 30, 2021 and is classified as Level 1 input. The restricted cash equivalent is a money market account that the Company opened in August 2020. The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy.

	Fair Value Measurements as of June 30, 2021		
	Level 1	Level 2	Level 3
Assets			
Restricted cash equivalents	$ 2,338	$ —	$ —
Total	2,338	—	—

	Fair Value Measurements as of December 31, 2020		
	Level 1	Level 2	Level 3
Assets			
Restricted cash equivalents	$ 2,338	$ —	$ —
	2,338	—	—
Liabilities			
Convertible notes payable			$ 24,694
Total	—	—	24,694

The Company did not have any financial instruments measured at fair value on a recurring basis as of June 30, 2021.

The change in the fair value of the derivative liabilities and convertible notes accounted for at fair value is summarized below.

	June 30, 2021	June 30, 2020
Fair value at beginning of the period	$ 24,694	$ —
Initial fair value of instruments issued	—	5,627
Change in fair value of instruments and accrued interest, net	288	1,444
Extinguishment of instruments held at fair value	(24,982)	—
Fair value at end of the period	$ -	$ 7,071

In order to determine the fair value of the convertible notes issued in December 2020, the Company utilized the probability-weighted expected return method ("PWERM"). The PWERM relies on a forward-looking analysis to determine the fair value. Under this method, discrete future outcomes, including an IPO and non-IPO scenarios, are weighted based on the estimated the probability of each scenario. The PWERM is used when discrete future outcomes can be predicted with reasonable certainty based on a probability distribution. The fair value estimate relied upon in the PWERM scenario was based on likelihood of achieving four liquidity events, i) an initial public offering ii) merger or acquisition of the Company given prevailing market conditions iii) change of control iv) maturity of the convertible notes. Estimates and assumptions impacting the fair value measurement include future value under the various conversion scenarios, discount rate, discount period, discount factor and probability of occurrence of each scenario, as best estimated by management. The estimated future value of the notes for each scenario is then discounted to present value using a discount rate. The future value was determined based on the estimated term to the event from valuation date as determined by management. The exit value in an IPO scenario is based on banker indications as well as an analysis of guideline companies that went public within the past few years that are broadly comparable to the Company. The exit value of an M&A scenario is determined by management with an estimated premium applied to the IPO value estimate. The discount rate, discount period, and probability of the occurrence of liquidity scenarios are estimates made by the management.

The convertible notes were measured at fair value one last time upon extinguishment on February 9, 2021 in connection with the Company's IPO.

Note 4. Other Financial Information

Inventory

Inventory consist of the following:

	June 30, 2021	December 31, 2020
Raw materials	$ 35,085	$ 4,865
Finished goods	1,097	—
Total	$ 36,182	$ 4,865

Property and Equipment, Net

	June 30, 2021	December 31, 2020
Construction in progress	$ 12,674	$ 15,308
Machinery and equipment	15,936	4,679
Website development costs	995	—
Furniture and fixtures	88	88
Leasehold improvements	507	501
Total, at cost	30,200	20,576
Accumulated depreciation and amortization	(2,047)	(1,168)
Property and equipment, net	$ 28,153	$ 19,408

Depreciation and amortization expense was $0.7 million and $0.9 million for the three and six months ended June 30, 2021, respectively, compared to $0.1 million and $0.1 million for the three and six months ended June 30, 2020, respectively. Construction in progress is related to the setup of manufacturing infrastructure and the purchase of long lead time manufacturing equipment as the Company grows its manufacturing capacity and invests in semi-automation. Construction in progress amounts recorded are not subject to depreciation as such assets are not yet available for their intended use.

Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2021	December 31, 2020
Professional fees	$ 1,367	$ 1,577
Accrued manufacturing and inventory purchases	14,107	1,165
Taxes	359	204
Payroll liabilities	1,866	604
Eiken liabilities	387	—
Early exercise liability	224	263
Accrued deferred offering costs	—	487
Other	362	145
Total	$ 18,672	$ 4,445

Note 5. Commitments and Contingencies

Commitments

License Agreement with Eiken Chemical Co., Ltd.

In July 2020, the Company entered into a patent license agreement (“Eiken Agreement”), with Eiken Chemical Co., Ltd. (“Eiken”). Pursuant to the terms of the Eiken Agreement, Eiken granted the Company a royalty bearing non-transferable, non-assignable, sublicensable (to the Company’s affiliates), non-exclusive license under certain patents, which the Company refers to collectively as the Eiken Licensed Patents, relating, in part, to loop-mediated isothermal amplification, to develop, make, use, sell, offer for sale and dispose of any reagent, product, kit, device, equipment and/or system for nucleic acid-based in-vitro diagnostic tests for detection of SARS-CoV-2, which causes COVID-19, which the Company collectively refers to as the Initial Licensed Products, in the United States. The Company also has limited have-made rights with respect to the Eiken Licensed Patents.

Under the terms of the Eiken Agreement, the Company also has an option to expand the license to the Eiken Licensed Patents for the Initial Licensed Products outside of the United States for a payment of additional fees. In addition, the Company also has an option to expand the license to the Eiken Licensed Patents for new targets beyond the purpose of testing COVID-19 in the United States, which the Company collectively refer to as the Additional Licensed Products, and together with the Initial Licensed Products, the Licensed Products, for a payment of a one-time fee for each Additional Licensed Product and an additional fee for the expansion of the licensed territory outside of the United States for each Additional Licensed Product.

As partial consideration of the rights granted to the Company under the Eiken Agreement, the Company made an upfront payment to Eiken of $24. The Company is also required to make an additional payment by July 2021 for $24 (based on the December 31, 2020 conversion ratio of 103.56 yen to one U.S. dollar). The Company recorded the upfront payment and second payment as research and development expense on the statement of operations for the year ended December 31, 2020. In April 2021, the Company paid the first installment of the world-wide license in the amount of $9. In addition, the Company is obligated to pay a royalty in the low single-digit percentage on total net sales of all Licensed Products, that will be recorded as a cost of goods sold. Royalty expense for the three months and six months ended June 30, 2021 were $0.4 million and $0.5 million, respectively, compared to $0 for the three and six months ended June 30, 2020.

The Eiken Agreement will terminate on the expiration date of the last to expire valid claim of the Eiken Licensed Patents in all countries, the latest of which is June 2031. The Company may also terminate the Eiken Agreement at any time upon a certain number of days' prior written notice to Eiken after Eiken has received the payment due July 2021 mentioned above and all royalties accrued up to the termination date. Eiken may terminate the Eiken Agreement upon (1) not receiving any royalties on Licensed Products for a certain period of time after the Company commences sale of such Licensed Product, (2) a breach by the Company or its affiliates that is not cured within a certain number of days after receiving written notice of the breach, (3) our bankruptcy or insolvency or certain other bankruptcy or insolvency events, (4) the assignment or attempt to assign the Eiken Agreement by the Company in violation of the Eiken Agreement or (5) a challenge by the Company or its affiliates of the validity of any of the Eiken Licensed Patents.

Technology Services Agreement with Jabil

On September 10, 2020, the Company entered into a technical services agreement ("Jabil TSA"), with Jabil, Inc. ("Jabil"), pursuant to which Jabil will use commercially reasonable efforts to perform certain technical services related to the development of components, assemblies and systems in relation to each project under the agreement as set forth in one or more statement of work, which may include the Company's COVID-19 test kit and any of its future product candidates.

The Company is obligated to pay Jabil all amounts as set forth in each statement of work, which will specify the timeline and schedule for the performance of each service, the compensation to be paid by the Company to Jabil and other relevant terms and conditions.

After the initial term of three years, the Jabil TSA will automatically be renewed for successive periods of one year unless a party provides the other party with notice of its intention not to renew the agreement at least 180 days prior to the expiration of the then current term. Either party may terminate the Jabil TSA at any time upon the mutual written consent of both parties. In addition, the agreement may be terminated by either party (a) at will upon at least 180 days' written notice to the other party, (b) for cause based on a material breach by the other party, subject to a 60-day cure period and (c) for certain bankruptcy or insolvency events enumerated under the agreement.

Manufacturing Services Agreement with Jabil

On September 10, 2020, the Company entered into a manufacturing services agreement ("Jabil MSA") with Jabil, pursuant to which Jabil will manufacture, test, pack and ship certain electronic assemblies and systems in accordance with the Company's specifications. Jabil may not subcontract any of its manufacturing services under the Jabil MSA without the Company's prior written consent. The Company is obligated to provide, on a monthly basis, a rolling 12-month forecast to Jabil as well as 12-months of historical aggregate end customer demand at the finished product level, when available, which will be used to constitute written purchase orders from the Company, and the Company is obligated to purchase the quantity of products that is required by the first four months of each forecast. Jabil is entitled to reject any purchase orders that are not placed in accordance with the forecast. As of June 30, 2021, the Company has an outstanding non-cancellable purchase commitment of $16.0 million related to the Jabil MSA.

The Company is obligated to pay Jabil upon the completion of test kit purchase orders based on a volume pricing matrix, pursuant to which Jabil will review the actual purchases during the then-ending quarter and compare against the forecasted orders in the upcoming quarter. If Jabil determines that the actual purchases correspond to a different pricing band in the volume pricing matrix, Jabil will either issue (a) a credit for any excess price paid by us if the actual price is lower than the invoiced price or (b) an invoice for any shortfall if the actual price is higher than the invoiced price. Jabil may adjust the volume pricing matrix to reflect changes in costs on the first anniversary of its notice to the Company that production qualification can commence, or after the addition of new equipment or labor. The parties will review the prices on a quarterly basis and may revise them based on applicable costs and expenses.

The agreement is for an initial term of three years and automatically renewed for successive periods of one year, subject to either party's notice of intent not to renew, delivered at least 180 days prior to the expiration of the then-current term. The Jabil MSA

may be terminated at any time upon the mutual written consent of the parties. In addition, the agreement may be terminated by either party (a) at will upon at least 180 days' written notice to the other party, (b) for cause based on a material breach by the other party, subject to a 30-day cure period and (c) for certain bankruptcy or insolvency events enumerated under the agreement.

Other Commitments

As of June 30, 2021, the Company has additional outstanding non-cancellable purchase commitments for $33.0 million for raw material purchases and fixed assets related to expanding the Company's manufacturing capacity.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not been subject to any claims or required to defend any action related to its indemnification obligations.

The Company's amended and restated certificate of incorporation contains provisions limiting the liability of directors, and its amended and restated bylaws provide that the Company will indemnify each of its directors to the fullest extent permitted under Delaware law. The Company's amended and restated certificate of incorporation and amended and restated bylaws also provide the Board with discretion to indemnify its officers and employees when determined appropriate by the Board. In addition, the Company has entered and expects to continue to enter into agreements to indemnify its directors and executive officers.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings arising out of the ordinary course of its business. Management is currently not aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

Note 6. Leases

The Company has operating leases for corporate offices, operations and research and development facilities. These leases have remaining lease terms of 1 to 3 years. The lease of operations and research and development facilities includes costs for utilities and common area maintenance which are not included in the calculation of lease payments.

Leases with an initial term of 12 months or less are not recorded on the balance sheets, and the Company recognizes lease expense for these leases on a straight-line basis over the lease terms. Operating leases with terms greater than 12 months are included in operating lease ROU assets and operating lease liabilities in the Company's balance sheets as of June 30, 2021 and December 31, 2020. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Maturities of lease liabilities as of June 30, 2021, are as follows:

	Operating Leases
Year ending December 31:	
2021 (July 2021 onwards)	$ 229
2022	259
2023	193
2024	33
2025	—
Total	714
Less: imputed interest	(86)
Present value of lease liabilities	628
Less: current portion	(374)
Lease liabilities, net of current portion	$ 254

The Company made payments of $0.2 million and $0.2 million during the six months ended June 30, 2021 and June 30, 2020, respectively, which are included as cash flow from operating activities on the statements of cash flows.

Additional information related to the Company's leases was as follows for the three and six months ended June 30:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating lease cost	$ 109	$ 109	$ 218	$ 218
Short-term lease cost	$ 312	$ 95	$ 627	$ 190

As of June 30, 2021 and December 31, 2020, the weighted-average remaining lease term for operating leases was 2.0 years and 2.4 years, respectively. As of June 30, 2021 and December 31, 2020, the weighted-average discount rate for operating leases was 13.1%.

Note 7. Convertible Notes Payable

2020A Notes

The Company entered into convertible promissory notes (the "2020A Notes") in June and July 2020, with several lenders, including current investors. The lenders provided in aggregate $11.1 million in cash consideration to the Company. The 2020A Notes accrued simple interest at 4% per annum that was due and payable upon the request of the holders of a majority of the then outstanding principal amount of the 2020A Notes on or after June 12, 2021.

Pursuant to the 2020A Notes, the outstanding principal balance and unpaid accrued interest was automatically convertible into equity shares in the next equity financing round of at least $10 million ("2020A Qualified Financing") at a price per share equal to the lower of (i) 80% of the price paid per share for equity securities by the investors in the 2020A Qualified Financing or (ii) the quotient resulting from dividing $95 million by the number of shares of outstanding common shares on a diluted basis immediately prior to the closing of the 2020A Qualified Financing. If the next financing was not a 2020A Qualified Financing ("2020A Non-Qualified Financing"), the holders of a majority of the outstanding principal of the 2020A Notes also had the option to convert the outstanding principal balance and unpaid accrued interest into equity shares issued in the 2020A Non-Qualified Financing on the same terms set forth for a 2020A Qualified Financing. In addition, if the Company consummated a change of control, it would be required to convert the outstanding principal balance of the 2020A Notes and any unpaid accrued interest into shares of a newly created series of preferred stock having the identical rights, privileges, preferences and restrictions as the Series B. Additionally, in the event that the 2020A Notes had not converted into equity securities by June 12, 2021, the outstanding principal and unpaid accrued interest of each of the 2020A Notes would have automatically converted into shares of Series B at a conversion price equal to the original issuance price.

In August 2020, the Company issued Series C for proceeds of approximately $58.7 million (see Note 8), which met the definition of a 2020A Qualified Financing. Additionally, the 2020A Notes and accrued and unpaid interest of $11.2 million were extinguished and converted into 2,593,110 shares of Series C at $4.3124 per share, which is 80% of the Series C issuance price of $5.3905. The Series C had a fair value of $5.3905 per share on the date of conversion. The Company extinguished the 2020A Notes at fair value along with the accrued interest of $44.

2020B Notes

The Company issued and sold convertible promissory notes (the "2020B Notes" and together with the "2020A Notes", the "2020 Notes") in December 2020, with several lenders, including current investors. The lenders provided an aggregate amount of $20.0 million in cash consideration to the Company. The 2020B Notes accrue simple interest at 0.15% per annum and this interest is due and payable upon the request of the holders of a majority of the then outstanding principal amount of the 2020B Notes on or after December 11, 2022.

The outstanding principal and unpaid accrued interest of each Note is convertible upon occurrence of one of the following events: Maturity or Change in Control. In the event of an equity financing including an IPO with proceeds of not less than $10.0 million ("2020B Qualified Financing"), 2020B notes automatically convert into equity securities sold in the 2020B Qualified Financing at 80% of the price paid for securities sold in the 2020B Qualified Financing. In the event of an equity financing or IPO of less than $10.0 million, the majority holders of the 2020B Notes have the option to treat the offering as a 2020B Qualified Financing at 80% of the price paid for securities sold in the round ("2020B Non-Qualified Financing"). In the case of maturity, all unpaid interest and principal shall be due and payable on the maturity date. If the notes remain outstanding on the maturity date, then the outstanding principal balance and any unpaid accrued interest is automatically converted in Series C Preferred stock based on the Series C original

issue price of $5.3905. In addition, if the Company consummates a change of control as defined in Note 8, the holders of the 2020B Notes will receive shares of the Company's common stock at 70% of the price paid for shares of common stock.

The 2020 Notes are considered freestanding instruments that qualify as liabilities under ASC Topic 480, Distinguishing Liabilities from Equity as the Company is committed to issue an instrument that ultimately may require a transfer of assets. The 2020 Notes were accounted for at fair value and re-measured at each reporting date. Accordingly, the Company classified the 2020 Notes as a liability at their fair value and adjusts the instruments to fair value at each balance sheet date until the 2020 Notes are converted. The Company recorded a change in the fair value of the 2020A Notes of $2.8 million recognized as remeasurement of derivative liabilities and convertible notes in other income (expense), net in the statements of operations prior to their extinguishment in August 2020. The Company recorded a change in the fair value of the 2020B Notes of $4.7 million recognized as remeasurement of derivative liabilities and convertible notes in other income (expense), net in the statements of operations during the year ended December 31, 2020.

The Company recorded a change in the fair value of the 2020B Notes of $0.3 million recognized as remeasurement of derivative liabilities and convertible notes in other income (expense), net in the statement of operations during the first quarter of 2021.

Conversion of Convertible Notes Payable

On February 9, 2021 upon the closing of the IPO, the 2020B Notes and accrued interest automatically converted into shares of common stock at a conversion price equal to 80% of the IPO price per share, which resulted in the issuance of 1,470,947 shares of common stock.

Note 8. Capital Stock

Redeemable Convertible Preferred Stock

Under the Company's amended and restatement certificate of incorporation, the Company is authorized to issue 14,382,437 shares of preferred stock designated as Series A, of which 3,274,913 were issued in October 2015.

On March 6, 2019, the Company amended and restated its certificate of incorporation to, among other things, increase its authorized shares of redeemable convertible preferred stock from 14,382,437 to 27,858,121 shares, of which 13,742,223 shares are designated as Series B and set forth the rights, preferences and privileges of the Series B. On July 24, 2019 the Company amended and restated its certificate of incorporation to increase its authorized shares of redeemable convertible preferred stock from 27,858,121 to 28,931,242, including increasing the shares designated as Series B to 14,815,344. On November 4, 2019, the Company amended and restated its certificate of incorporation to increase its authorized shares of redeemable convertible preferred stock from 28,931,242 to 29,208,635, including increasing the shares designated as Series B to 15,092,737.

In March 2019, the Company entered into an agreement with new and existing preferred stockholders, to issue 1,608,300 shares of Series B for $7.5 million in gross proceeds. In addition, as discussed in Note 7, the Company converted all outstanding 2018 Notes and related accrued interest in the amount of $4.1 million into 1,097,048 shares of Series B. From June to August 2019, the Company entered into agreements with new and existing preferred stockholders, to issue an additional 731,824 shares of Series B for $3.4 million in gross proceeds. The Company incurred approximately $83 of issuance costs related to Series B during the year ended December 31, 2019, which has been netted against the gross proceeds.

On January 9, 2020, the Company amended and restated its certificate of incorporation to increase its authorized shares of redeemable convertible preferred stock to 45,389,864 including increasing the shares designated as Series B to 31,273,966. On August 6, 2020, the Company amended and restated its certificate of incorporation to increase its authorized shares of redeemable convertible preferred stock to 103,355,827, of which 30,996,574 shares are designated as Series B and 58,243,355 of shares are designated as Series C and set forth the rights, preferences and privileges of Series C.

In August 2020, the Company entered into an agreement with new and existing preferred stockholders, to issue 13,512,578 shares of Series C for $69.8 million in proceeds from the sale of Series C and the conversion of convertible notes and related accrued interest in the amount into 2,593,110 shares of Series C.

On February 9, 2021 in connection with the closing of the IPO, all shares of redeemable convertible preferred stock converted into 23,978,747 shares of common stock.

On February 9, 2021, the Company amended and restated its certificate of incorporation to authorize two classes of stock, respectively, common stock and preferred stock. The total number of shares which the Company is authorized to issue is 210,000,000

shares. 200,000,000 shares of which shall be Common Stock, having a par value per share of $0.001. 10,000,000 shares of which shall be Preferred Stock, having a par value per share of $0.001.

The Company has not issued any preferred stock since the closing of the IPO.

As of December 31, 2020, the Company's redeemable convertible preferred stock consisted of the following:

	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Liquidation Value
Series A	14,115,898	3,274,913	$ 15,020	$ 16,763
Series B	30,996,574	7,191,256	33,406	33,523
Series C	58,243,355	13,512,578	72,654	72,840
Total	103,355,827	23,978,747	$ 121,080	$ 123,126

Dividends

The Company may not declare, pay or set aside any dividends on shares of the Company unless the holders of the outstanding Series C first receive a dividend on each outstanding share of Series C in an amount equal to the dividend payable per share if all participating shares had been converted into common stock multiplied by the number of shares of common stock issuable upon the conversion of Series C. After payment or setting aside dividends to Series C, Series B are entitled to receive, prior and in preference to holders of common stock, a dividend on each outstanding share of Series B in an amount equal to the dividend payable per share if all participating shares had been converted into common stock multiplied by the number of shares of common stock issuable upon the conversion of Series B. After payment or setting aside dividends to Series B, Series A are entitled to receive, prior and in preference to holders of common stock, a dividend on each outstanding share of Series A in an amount equal to the dividend payable per share if all participating shares had been converted into common stock multiplied by the number of shares of common stock issuable upon the conversion of Series A.

As of June 30, 2021, the Board had not declared any dividends.

Liquidation Preference and Redemption

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a deemed liquidation event, the holders of shares of Series C then outstanding are entitled to be paid before any payment is made to the holders of the Series B, Series A or common stock, the Series C liquidation preference, which is equal to the greater of (i) one times the Series C original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series C been converted into common stock. Upon satisfaction of Series C liquidation preference, the Series B liquidation preference, which is equal to the greater of (i) the per share liquidation preference plus all declared but unpaid dividends or (ii) the amount per share as would be payable had all shares of Series B been converted into common stock, is paid prior to any other preferences. Upon the satisfaction of the Series B liquidation preference, the Series A liquidation preference, which is equal to the greater of (i) the per share liquidation preference plus all declared but unpaid dividends or (ii) the amount per share as would be payable had all shares of Series A been converted into common stock, is paid prior to any additional preferences. Following the satisfaction of the liquidation preferences, all holders of shares of common stock participate in any remaining distribution on a pro rata basis based on the number of shares of common stock then held. As of December 31, 2020, the liquidation preference per share for Series A, Series B, and Series C was $5.1185, $4.6616 and $5.3905 respectively.

Each of the following events is considered a "Deemed Liquidation Event" unless the holders of at least a majority of the outstanding shares of redeemable convertible preferred stock on an as-converted basis elect otherwise by written notice sent to the Company at least five (5) days prior to the effective date of any such event:

(a) a merger or consolidation in which (i) the Company is a constituent party or (ii) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation;

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company; or

(c) a share purchase, share exchange or tender offer in which at least a majority, by voting power, of the shares of capital stock of the Company are transferred to another person.

Conversion

Each share of redeemable convertible preferred stock is automatically convertible into common stock at its then-effective conversion price (discussed below) (i) upon the vote or written consent of the holders of at least a majority of the then outstanding shares of redeemable convertible preferred stock on an as-converted basis, or (ii) upon the completion of a firm underwritten public offering of the Company's common stock with gross proceeds of at least $50.0 million.

In addition, each share of the Company's redeemable convertible preferred stock are convertible, at the option of the holder, into shares of common stock by dividing the initial conversion prices by the conversion price in effect at the time of conversion.

The following table summarizes the number of shares of common stock into which each share of redeemable convertible preferred stock can be converted as of December 31, 2020:

	Initial Conversion Price	Conversion Price as of December 31, 2020	Conversion Ratio to Common Stock
Series A	$ 5.1185	$ 5.1185	1
Series B	$ 4.6616	$ 4.6616	1
Series C	$ 5.3905	$ 5.3905	1

The conversion price of Series A, Series B, and Series C is subject to adjustment for recapitalization (i.e. stock dividends, stock splits, reorganization, reclassification, combination of shares), or upon the issuance of shares at a price less than the then current conversion price.

Voting

The holder of each share of redeemable convertible preferred stock is entitled to one vote for each share of common stock into which it would convert. The holders of Series A, exclusively and as a separate class, are entitled to elect one director. In addition, the holders of record of the shares of Series B, exclusively and as a separate class, are entitled to elect two directors. The holders of Series C, exclusively and as a separate class on an as-converted basis, are entitled to elect one director.

Redemption

The convertible preferred stock is not redeemable at the option of the holders.

Common Stock

As of December 31, 2018, the Company was authorized to issue 28,716,724 shares of $0.001 par value common stock. In March 2019, the Company's certificate of incorporation was amended and restated to increase the number of authorized shares of common stock from 28,716,724 to 50,000,000. In July 2019, the number of authorized shares of common stock was increased to 51,000,000. In November 2019, the number of authorized shares of common stock was increased to 52,000,000. In January 2020, the number of authorized shares of common stock was increased to 75,000,000. Similarly, in August 2020, the certificate of incorporation was amended to increase the number of shares authorized for issuance to 150,000,000 shares of common stock.

On February 9, 2021, the Company closed its IPO of 10,350,000 shares of its common stock, including 1,350,000 shares of common stock issued pursuant to the full exercise of the underwriters' option to purchase additional shares in the IPO, at a price to the public of $17.00 per share. The net proceeds to the Company from the IPO were $159.9 million, after deducting underwriting

discounts and commissions of $12.3 million and offering expenses of $3.7 million. In addition, the Company's outstanding 2020B convertible notes converted into 1,470,947 shares of common stock.

Common stockholders are entitled to dividends as and when declared by the Board, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

The Company had common shares reserved for future issuance upon the exercise or conversion of the following:

	June 30, 2021	December 31, 2020
Redeemable convertible preferred stock	—	23,978,747
Common stock option grants issued and outstanding under 2014 Plan	4,409,153	4,587,700
Common shares issuable on conversion of convertible notes payable	—	1,470,947
Common stock reserved for issuance under 2021 Plan (which superseded the 2014 Plan)	3,505,556	206,012
Common stock option grants issued and outstanding under 2021 Plan	596,509	—
Restricted common stock units issued and outstanding	1,097,935	—
Common stock reserved for issuance under ESPP	750,000	—
Total common shares reserved for future issuance	10,359,153	30,243,406

Note 9. Equity Incentive Plan

In 2014, the Company adopted the 2014 Equity Incentive Plan (the "2014 Plan") to permit the grant of share-based awards, such as stock grants and incentives and non-qualified stock options to employees, directors, consultants and advisors. The Board has the authority to determine to whom awards will be granted, the number of shares, the term and the exercise price. Awards granted under the 2014 Plan have a term of 10 years and generally vest over a four-year period with straight-line vesting and a 25% one-year cliff. As of December 31, 2020, a total of 5,512,742 shares of the Company's common stock were reserved for issuance under the 2014 Plan, of which 206,012 were available for grant

In January 2021, the Board adopted the 2021 Plan. The stockholders approved the 2021 Plan in January 2021, and it became effective upon the execution of the underwriting agreement for the IPO on February 4, 2021. Under the 2021 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock or cash-based awards to individuals who are then employees, officers, directors or consultants of the Company. A total of 5,200,000 shares of common stock were approved to be initially reserved for issuance under the 2021 Plan. In addition, the number of shares of common stock available for issuance under the 2021 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2021 Plan, beginning with January 1, 2022 and ending with January 1, 2031, by an amount equal to 5% of the outstanding number of shares of common stock on December 31st of the preceding calendar year or such lesser amount as determined by the Board. No further grants will be made under the 2014 Equity Incentive Plan.

Restricted Stock Units

Restricted stock units ("RSUs") are generally subject to a 4 year vesting period, with 25% of the shares vesting approximately one year from the vesting commencement date and quarterly thereafter over the remaining vesting term.

The Company had the following activity for RSUs for the three and six months ended June 30, 2021:

	Underlying Shares	Weighted-Average Grant Date Fair Value	Aggregate Fair Value
Balance as of December 31, 2020	—	—	—
Granted	264,345	$ 12.79	$ 3,380,272
Vested	—	—	—
Canceled or forfeited	—	—	—
Balance as of March 31, 2021	264,345	$ 12.79	$ 3,380,272
Granted	833,590	$ 4.85	$ 4,042,912
Vested	—	—	—
Canceled or forfeited	—	—	—
Balance as of June 30, 2021	1,097,935	$ 6.76	$ 7,423,184

Stock Options

A summary of stock option activity for the three and six months ended June 30, 2021 is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2020	4,587,700	$ 1.51	9.2	$ 3,152
Granted	634,093	17.00	—	—
Exercised	(37,760)	0.82	—	596
Cancelled	(32,480)	17.00		—
Balance as of March 31, 2021	5,151,553	$ 3.32	9.1	$ 48,122
Granted	—	—	—	—
Exercised	(134,398)	0.95	—	753
Cancelled	(11,493)	8.19	—	—
Balance as of June 30, 2021	5,005,662	$ 3.42	8.8	$ 22,512
Options vested and expected to vest as of June 30, 2021	5,005,662	$ 3.42	8.8	$ 22,512
Options vested and exercisable as of June 30, 2021	1,198,274	$ 1.52	8.2	$ 6,421

The aggregate intrinsic value of options exercised was $0.8 million and $1.3 million for the three and six months ended June 30, 2021. The aggregate intrinsic value of options exercised was $0 for the three and six months ended June 30, 2020.

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions on a weighted-average basis for three and six months ended:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Estimated fair value of common stock	$ -	$ 0.73	$ 17.00	$ 0.73
Expected term (in years)	—	6.05	5.94	6.05
Risk-free interest rate	0.0%	0.4%	0.6%	0.4%
Dividend yield	—	—	—	—
Volatility	0.0%	43.3%	46.9%	43.3%

Common stock fair value—Prior to the IPO the fair value of the Company's common stock is determined by the Board with assistance from management. The Board determines the fair value of common stock by considering independent valuation reports and a number of objective and subjective factors, including valuations of comparable companies, sales of redeemable convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook.

Dividend yield of zero—The Company has not declared or paid dividends.

Risk-free interest rates—The Company applies the risk-free interest rate based on the US Treasury yield for the expected term of the option.

Expected term—The Company calculated the expected term as the average of the contractual term of the option and the vesting period for its employee stock options.

Expected volatility—Since the Company does not have sufficient stock price history to estimate the expected volatility of its shares, the expected volatility is calculated based on the average volatility for a peer group in the industry in which the Company does business.

The weighted-average grant date fair value of the options granted as calculated using the Black-Scholes option-pricing model was $7.52 and $0.30 per share for the six months ended June 30, 2021 and June 30, 2020, respectively. The Company did not grant options during the three month period ended June 30, 2021

Total compensation cost for share-based payment arrangements recognized were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of products sold	$ 208	$ -	$ 260	$ -
Research and development	291	31	421	67
Selling, general and administrative	446	28	792	50
	$ 945	$ 59	$ 1,473	$ 117

Total compensation costs as of June 30, 2021 related to non-vested awards to be recognized in future periods was $6.1 million and is expected to be recognized over the weighted-average period of 1.4 years.

Employee Stock Purchase Plan

The ESPP provides eligible employees with an opportunity to purchase common stock from the Company at a discount through accumulated payroll deductions. The ESPP will be implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, the Company's Board of Directors may specify offerings but generally provides for a duration of 6 months. The first purchase period began in February 2021 and will close in August 2021.

The purchase price will be specified pursuant to the offering, but cannot, under the terms of the ESPP, be less than 85% of the lower of the fair market value per share of the Company's common stock on either the offering date or on the purchase date. The ESPP also includes a six month look-back provision for the purchase price of the stock price on the purchase date is less than the stock price on the offering date.

In February 2021, the Company's employees enrolled in the offering period to purchase a variable number of shares of its common stock under the ESPP at the purchase date. The shares were measured at grant date using with a weighted-average fair value of $5.34 per share. During the three and six months ended June 30, 2021, the Company recorded $0.1 million of stock-based compensation related to its ESPP. There was less than $0.1 million of unrecognized stock-based compensation expense for the three and six month ended June 30, 2021, related to the ESPP that is expected to be recognized over an average vesting period of 0.14 years.

The fair value of shares to be issued under the Company's ESPP was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions on a weighted-average basis for three months ended:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Estimated fair value of common stock	$ -	$ -	$ 17.00	$ -
Expected term (in years)	—	—	0.5	—
Risk-free interest rate	0.0%	0.0%	0.1%	0.0%
Dividend yield	—	—	—	—
Volatility	0.0%	0.0%	56.4%	0.0%

Note 10. Income Taxes

The Company did not record a provision or benefit for income taxes during the three and six months ended June 30, 2021 and 2020. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

Note 11. Retirement Plan

In December 2017, the Company adopted the Lucira Health, Inc. 401(k) Plan which allows eligible employees after one month of service to contribute pre-tax and Roth contributions to the plan, as allowed by law. The Company currently does not match employee contributions.

Note 12. Related Parties

The Company issued Convertible Notes to related parties for a total of $11.5 million during the year ended December 31, 2020, and carried the same terms as those disclosed in Note 7. The Convertible Notes interest expense was not significant during the year ended December 31, 2020. The Company held $8.7 million in 2020B Notes to related parties as of December 31, 2020. In connection with the IPO on February 9, 2021, all outstanding convertible notes were converted into shares of common stock.

The Company incurred less than $0.1 million in consulting expenses with individuals related to an executive officer of the Company during the six months ended June 30, 2021 and June 30, 2020.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The interim condensed financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission on March 31, 2021 (the "2020 Annual Report"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2020 Annual Report, "Part II. Item 1A. Risk Factors" in this report, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

When used in this report, all references to "Lucira," the "company," "we," "our" and "us" refer to Lucira Health.

Overview

We are a medical technology company focused on the development and commercialization of transformative and innovative infectious disease test kits. We have developed a testing platform that produces centralized-laboratory-accurate molecular testing in a single-use and consumer-friendly test kit that is powered by two AA batteries and fits in the palm of a hand. We designed our test kits to provide accurate, reliable and on-the-spot molecular test results anywhere and at any time. We believe the COVID-19, pandemic has shown the infectious disease testing infrastructure in the United States was not designed to accommodate the immediate demands of infectious disease control on a mass-population scale. There are currently not enough testing options that provide on-the-spot, accurate results at an affordable price point. Mass-population infectious disease testing requires a testing platform that can provide accurate and clinically relevant results on-the-spot, be affordably mass produced, portable and easy-to-use anywhere. Our LUCIRA COVID-19 All-In-One Test Kit used in the point-of-care, or POC, and prescription at-home settings and our LUCIRA CHECK IT COVID-19 Test Kit used over-the-counter, or OTC, utilize identical components and are referred to as test kit or COVID-19 test kit. Our test kit is designed to provide a clinically relevant COVID-19 result within 30 minutes from sample collection. We believe, at scale, it will be an affordable, mass-population testing solution. Our initial focus is within respiratory diseases, starting with COVID-19 and influenza A and B virus indications. Leveraging our early work on the detection of sexually transmitted infections, specifically assays to detect chlamydia and gonorrhea, we have been optimizing and evaluating these assays for possible future commercialization.

Our first clinical trial was conducted among symptomatic individuals and demonstrated the molecular accuracy of our COVID-19 test kit as comparable to the known high sensitivity Hologic Panther Fusion SARS-CoV-2 assay, or Hologic Panther Fusion, was initiated in September 2020 and supported our first Emergency Use Authorization, or EUA. The Hologic Panther Fusion is a high sensitivity molecular assay due to its low Limit of Detection, or LoD, as labeled in its U.S. Food and Drug Administration , or FDA, emergency use authorization, or EUA. In this clinical trial, we collected samples from 101 subjects, tested the samples head-to-head against the Hologic Panther Fusion and achieved 94.1% positive percent agreement (96.0% with discrepant testing) and 98.0% negative percent agreement. Our strong clinical performance was enabled by our LoD of 900 copies per mL of viral transfer media equivalent, or cps / mL VTM equivalent, which allows our COVID-19 test kit to detect viral genetic material in orders of magnitude better than antigen tests. In addition, our COVID-19 test kit is easy-to-use. Specifically, 100% of patients successfully performed self-testing at home using our COVID-19 test kit in less than two minutes in a human usability study we conducted with 398 users at research facilities in Sunnyvale and Fresno, California. The measure for successful performance was the ability to collect a nasal specimen and start the test running on the first try, either without having to look back at the directions or with only one look back. On November 17, 2020, we received an EUA, from the FDA for (1) prescription at-home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider and (2) use at the POC, with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC. Our test kit was the first FDA-authorized, under an EUA, COVID-19 test that allows patients to test themselves and receive results at home. Our prescription at-home use indication does not require healthcare provider telehealth or video observation.

In December 2020, we initiated a follow-on clinical trial among asymptomatic individuals to support both a new EUA submission for OTC non-prescription use, as well as an EUA amendment to our initial EUA to expand the indicated population to include asymptomatic individuals. We refer to our clinical trial among symptomatic individuals and our follow-up clinical trial among asymptomatic individuals as our Community Testing Studies. The asymptomatic study enrolled a total of 303 individuals, including 81 asymptomatic positives, and again utilized the Hologic Panther Fusion as the comparator. Results of the follow-on asymptomatic study showed no statistical difference in our test performance compared to the first study among symptomatic individuals. Hence, simply increasing the sample and confidence in our molecular accuracy as compared to the known high sensitivity

Hologic Panther Fusion assay. Our accuracy across both Community Testing Studies as compared to the Hologic Panther Fusion was 96% across all 404 samples. Our sensitivity, or positive percent agreement (PPA), was 92% across all 132 positive samples. Excluding samples with very low levels of virus that possibly were no longer infectious, our sensitivity, or PPA was 97%. Our specificity, or negative percent agreement (NPA) across both studies was 98%.

We submitted EUA applications to the FDA for the expansion of our current EUA to include asymptomatic individuals and OTC use in February 2021. On April 9, 2021, we received our first FDA EUA authorization for OTC non-prescription use among symptomatic and asymptomatic individuals aged 14 and older (with self-collection) and children aged 2-13 (with parent collection). Our COVID-19 test kit is the first single-use molecular test that provides polymerase chain reaction, or PCR, quality molecular accuracy to receive FDA EUA authorization. On June 30, 2021, we withdrew our pending EUA application with the FDA that was intended to expand our current prescription EUA for suspected symptomatic individuals to include asymptomatic individuals because we decided instead to refocus on an FDA 510(k) submission. On April 26, 2021, we received authorization with conditions from Health Canada for our LUCIRA CHECK IT test kit. The conditions were removed on June 1, 2021. To facilitate public health reporting for OTC users, we have developed a text based secure web portal to provide verified test results in the form of a LUCI Pass back to a user's phone, as well as transmit results to relevant public health authorities. Late in the second quarter of 2021, we decided to temporarily halt online sales of our LUCIRA CHECK IT test kit as we prioritized distribution to our partnerships. We intend to reactivate online ordering again in the second half of 2021.

We plan to develop a combination COVID-19 and influenza A and B viruses test kit for OTC use and later our influenza test kit, for OTC use. We also plan to leverage our early assay work on the detection of sexually transmitted infections and other respiratory infections to evaluate for possible expansion of our testing menu.

Since inception and prior to the COVID-19 pandemic, we focused our research and development efforts on developing our molecular nucleic acid amplification technology for use in our influenza test kit, for which we have received government grants from the Biomedical Advanced Research and Development Authority, or BARDA, to assist with development. As a result of the COVID-19 pandemic and based on clinical trials of our influenza test kit to date, we refocused our near-term business strategy to respond to the COVID-19 pandemic and focus on the development and commercialization of our COVID-19 test kit.

Since inception through June 30, 2021, we have generated $17.2 million of revenue from the sales of our test kits. Prior to the closing of our IPO, we had financed our operations principally from net proceeds of approximately $137.3 million from sales of our preferred stock, issuances of convertible debt and common stock purchases. On February 9, 2021, we closed our IPO of 10,350,000 shares of common stock, including 1,350,000 shares issued pursuant to the full exercise of the underwriters' option to purchase additional shares in the IPO, at a price to the public of $17.00 per share. The net proceeds to us from the IPO were $159.9 million, after deducting underwriting discounts and commissions of $12.3 million and offering expenses of $3.7 million.

We have historically incurred substantial net losses as we continue to develop and begin commercializing our COVID-19 test kit and we expect to incur additional losses and increased expenses in future periods. As of June 30, 2021, we had an accumulated deficit of $93.2 million.

Since the second quarter of 2020, we have primarily devoted our resources to the research, development, manufacturing and commercialization of our COVID-19 test kit. Research and development activities related to our test kits, including the COVID-19 test kit, include clinical, regulatory and manufacturing process initiatives. We expect that our sales and marketing, research and development, regulatory and other expenses will continue to increase as we expand our marketing efforts to promote adoption of our COVID-19 test kit, build relationships with our customers, obtain regulatory clearances or approvals for current and any future test kits, qualify manufacturing expansion, and conduct clinical trials. In addition, we expect our general and administrative expenses to increase due to the additional costs associated with scaling our business operations as well as being a public company, including legal, accounting, insurance, Nasdaq and SEC compliance, investor relations and other expenses. As a result, we will require substantial capital to fund manufacturing expansion, inventory purchases and expenses related to our operating activities, including selling, general and administrative expenses, as well as research and development.

In 2020, we entered into license and manufacturing and services agreements. For a more detailed description of our license and manufacturing and services agreements, see Note 5 to our unaudited condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Factors Affecting Our Business

We believe the following significant factors affect our business:

- ***Approval and Market Adoption of Our Test Kits.*** Our commercial success, including acceptance and use of our COVID-19 test kit, will depend upon a number of factors, some of which are beyond our control, including the receipt of regulatory approvals for additional indications of our COVID-19 test kit and timing thereof, size of the market opportunity, demand from the public and members of the medical community for our COVID-19 test kit and rate of adoption of our COVID-19 test kit. The commercial success of our COVID-19 test kit was initially dependent upon physicians and healthcare providers accepting and adopting our test kit. Once the OTC EUA was received, the universe of potential customers expanded to include the general public, corporations and other entities that use our test for employee, member and customer testing as well as certain international customers. Our ability to successfully execute on this strategy, and thereby increase our revenue, will in part drive our results of operations and impact on our business.

- ***Cost of Revenue.*** The results of our business will depend in part on our ability to establish and increase our gross margins by effectively managing our costs to produce our test kits, including, initially, our COVID-19 test kit. To better meet the market demand for COVID-19 diagnostic testing, a key part of our growth strategy includes expanding our current manufacturing capacity and automating much of the manufacturing process. Our test kits have been designed for automated production. Eventually, we could expand manufacturing to additional locations around the world to further our manufacturing capacity and reach.

- ***Status of COVID-19 Pandemic.*** Given the unpredictable nature of the COVID-19 pandemic, the potential size of the COVID-19 diagnostic testing market and the timing of its development are highly uncertain. The FDA issued two EUAs in December 2020 and third EUA in February 2021 for COVID-19 vaccines. The widely administered use of efficacious vaccines or new therapeutic treatment for COVID-19 may reduce the demand for COVID-19 diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow. However, we believe COVID-19, like influenza, will remain endemic for the foreseeable future and there will be a continued need for COVID-19 testing even after an effective vaccine has been widely distributed and compliantly administered. We believe this is largely due to the COVID-19 pandemic resulting in hyper-sensitivity to symptoms and broader awareness of the disease. Furthermore, the emergence and spread of new variant strains of COVID-19 and future spikes of COVID-19 infections may increase demand for testing. We continue to perform routine surveillance of emerging variants by evaluating reactivity against sequence databases. Based on our results, our COVID-19 test kit is reactive to the variants currently highlighted by the CDC and the WHO, including the Delta variant. Our future success is substantially dependent on the manner in which the market for COVID-19 diagnostics develops and grows as well as regional fluctuations in COVID-19 disease prevalence.

- ***Seasonality.*** Our ability to accurately forecast demand for our test kits could be negatively affected by many factors, including seasonal demand. We may experience fluctuations in customer and user demand based on seasonality, which for COVID-19, remains unknown. However, for example, because influenza typically occurs in the fall and winter seasons, we expect our forecasts of inventory for these seasons to reflect a significant increase in inventory relative to our forecasts for the spring and summer seasons. 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.

Operations

Our corporate headquarters are currently located in Emeryville, California, where we lease 6,353 square feet of office, research and development space pursuant to a lease agreement that expires in March 2022. Pursuant to the same lease agreement, we lease an additional 4,211 square feet of office and development space in Emeryville, California that expires in January 2024. In July 2021, we leased and additional 13,267 square feet of office, research and development space in Emeryville, California that expires in June. We believe these facilities are adequate to meet our needs in the near term and that additional space can be obtained on commercially reasonable terms as needed.

As of June 30, 2021, we had 84 full-time employees and 40 contractors. Our employees are primarily located in Emeryville, California. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that we have good relations with our employees.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Critical Accounting Policies and Significant Management Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses.

We evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation, on an ongoing basis. We base our estimates on 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.

There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis – Critical Accounting Policies and Significant Management Estimates" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, except for those accounting subjects discussed in Note 2 to the unaudited condensed financial statements titled Recently Adopted Accounting Standards included in this Quarterly Report on Form 10-Q.

Results of Operations

The following table sets forth the significant components of our results of operations for the periods presented.

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020			2021	2020		
	(In thousands)				(In thousands)			
Net sales	$ 12,439	$ —	$ 12,439	100%	$ 16,955	$ —	$ 16,955	100%
Cost of products sold	12,505	—	12,505	100	17,873	—	17,873	100
Gross loss	(66)	—			(918)	—		
Operating expenses:								
Research and development	10,117	4,574	5,543	121	16,399	7,315	9,084	124
Selling, general and administrative	6,100	931	5,169	555	12,200	1,559	10,641	683
Total operating expenses	16,217	5,505			28,599	8,874		
Loss from operations	(16,283)	(5,505)			(29,517)	(8,874)		
Other income (expense), net:								
Grant income	79	335	(256)	(76)	281	1,977	(1,696)	(86)
Interest income (expense)	4	(10)	14	(140)	1	(10)	11	(110)
Remeasurement of derivative liabilities and convertible notes	—	(1,444)	1,444	(100)	(281)	(1,444)	1,163	(81)
Total other income (expense), net	83	(1,119)			1	523		
Net loss	$ (16,200)	$ (6,624)			$ (29,516)	$ (8,351)		

Net Sales, Cost of Products Sold and Gross Loss

We began to generate sales during December 2020 after we received an EUA from the FDA for POC and prescription-at-home use of our COVID-19 test kit. The increase in revenues is due to increased volume in units sold whereas we did not conduct revenue generating activities during the same period in 2020. We currently derive all of our revenue from the sales of our test kits in accordance with the provisions of Accounting Standards Codifications, or ASC, Topic 606, Revenue from Contracts with Customers. Our product revenue is recognized upon the transfer of control of our test kits to the customer. We may experience fluctuations in customer and user demand based on seasonality, which for COVID-19 remains unknown. As a result, our revenue may fluctuate from quarter to quarter due to seasonality. Our revenue may also fluctuate from quarter-to-quarter due to a variety of factors, including the

availability of reimbursement, the size and success of our sales force and the number of businesses and healthcare providers who are aware of and use our tests. Our net sales were primarily driven by access to the OTC channel through our EUA authorization, resulting in direct sales to include domestic testing providers, distributors and businesses and international distributors.

Much like our revenues, we began to generate cost of products sold in December 2020 after we received an EUA from the FDA for POC and prescription-at-home use of our COVID-19 test kit whereas we did not conduct revenue generating activities during the same period in 2020. Costs of products sold include cost of raw materials and supplies for our finished test kits, direct labor, contract manufacturing fees, in-bound and internal shipping and handling costs incurred in manufacturing our test kits, royalties, allocated overhead, and depreciation expense. For the three and six months ended June 30, 2021, we sold inventory amounting to less than $0.1 and $1.0 million, respectively, that was previously written off prior to the receipt of EUA.

We expect that our costs of revenues and cost of products sold will increase on an absolute basis as the number of COVID-19 test kits we sell increases. We expect that the cost per test kit will decrease over time due to anticipated volume discounts on outsourced manufacturing costs, materials and shipping costs, and through other volume efficiencies we may gain as the number of test kits manufactured increases. We expect our costs of revenue to fluctuate from quarter to quarter.

Research and Development

Research and development expenses increased $5.5 million, or 121%, and $9.1 million, or 124%, in the three and six months ended June 30, 2021, compared to the same period in 2020. This increase was primarily due to increased expenses related to our development and clinical activities to support new products, our submission of an EUA for OTC use with respect to our COVID-19 test kit and to support manufacturing activities. For the three months ended June 30, 2021, we supported research and development activities such as test kit development and testing, and validation of manufacturing activities related to our COVID-19 test kit through increased personnel-related expenses of $0.9 million, third-party professional services of $2.1 million, and supplies and materials of $0.5 million compared to the same period in 2020. For the six months ended June 30, 2021, we supported research and development activities such as test kit development and testing, clinical trials and validation of manufacturing activities related to our COVID-19 test kit through increased personnel-related expenses of $1.4 million, third-party professional services of $4.3 million, and supplies and materials of $0.6 million compared to the same period in 2020.

Selling, General and Administrative

Selling, general and administrative expenses increased $5.2 million, or 555%, and $10.6 million, or 683%, in the three and six months ended June 30, 2021, respectively, compared to the same period in 2020. For the three months ended June 30, 2021, this increase was primarily due to an increase in headcount and personnel-related expenses of key, executive-level employees of $1.8 million and professional expenses of $0.8 million to support our commercial activities, and public company insurance of $1.2 million. For the six months ended June 30, 2021, this increase was primarily due to an increase in headcount and personnel-related expenses of key, executive-level employees of $3.7 million and professional expenses of $3.4 million to support our commercial activities, and public company compliance and insurance of $2.1 million.

Grant Income

Grant income decreased $0.3 million, or 76%, and $1.7 million, or 86%, in the three and six months ended June 30, 2021 compared to the same period in 2020. This decrease was primarily due to the stoppage of BARDA billing in June 2020 as we shifted our near-term business strategy from the development of influenza test kits to respond to the COVID-19 pandemic.

Remeasurement of Derivative Liabilities and Convertible Notes

The change in remeasurement of derivative liabilities and convertible notes decreased $1.4 and $1.2 million during the three and six months ended June 30, 2021, respectively, compared to the same period in 2020 primarily due to change in fair value upon conversion of the 2020B Notes to common stock.

Liquidity and Capital Resources

Based on our current planned operations, we expect that our existing cash, including net proceeds from our IPO, will enable us to fund our business operations for at least 12 months from the date hereof. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Sources of Liquidity

We have incurred net losses since our inception. For the three months and six months ended June 30, 2021, we incurred a net loss of $16.2 million and $29.5 million, respectively, compared to $6.6 million and $8.4 million, respectively for the same periods in 2020. We expect to incur additional losses and increased operating expenses in future periods. As of June 30, 2021, we had an accumulated deficit of $93.2 million. To date, we have generated only limited grant income and product revenue, and we may never achieve revenue sufficient to offset our expenses.

Prior to our IPO, our primary sources of capital were from the sales and issuances of convertible notes, shares of preferred stock, grant income, and to a lesser extent, option exercises.

In December 2020, we issued and sold 2020B Notes in the aggregate principal amount of $20.0 million in a private placement, which, in addition to the accrued interest thereon, automatically converted into shares of our common stock at a conversion price equal to 80% of the IPO price per share. On February 9, 2021, we closed our IPO of 10,350,000 shares of common stock, including 1,350,000 shares issued pursuant to the full exercise of the underwriters' option to purchase additional shares in the IPO, at a price to the public of $17.00 per share. The net proceeds to us from the IPO were $159.9 million, after deducting underwriting discounts and commissions of $12.3 million and offering expenses of $3.7 million. As of June 30, 2021, we had $161.7 million in cash.

Off-Balance Sheet Arrangements

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

Uses of Liquidity

Our primary uses of cash are to fund our operations as we continue to grow our business. We will require a significant amount of cash to fund capital expenditures, inventory purchases and timing of accounts receivable as we grow our commercial infrastructure. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our selling, general and administrative expenses, and research and development expenses will continue to increase as we seek additional regulatory approvals and further develop test kits, increase our test kit manufacturing volume, expand our marketing efforts and increase our internal sales force to drive increased adoption of our test kits.

In January 2015, we entered into a lease for office, research and development space located in Emeryville, California that expires in March 2022. Pursuant to the same lease agreement, we leased additional square feet of office and development space in Emeryville, California that expires in January 2024. For the 12-month period ending June 30, 2022, we project that our fixed commitments will include $0.4 million of lease payments.

Pursuant to the patent license agreement, or the Eiken Agreement, with Eiken Chemical Co., Ltd., or Eiken, that we entered into in July 2020, we are obligated to make milestone payments upon the achievement of specified regulatory milestones as well as royalty payments. The future payments under this agreement are contingent upon future events, such as our achievement of specified milestones and product sales. We are currently unable to estimate the timing or likelihood of achieving these milestones or generating future test kit sales. See Note 5 to our unaudited condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

As of June 30, 2021, we had non-cancellable purchase commitments of $49.0 million, consisting primarily of $33.0 million of raw material purchase commitments and fixed assets related to expanding our manufacturing capacity, and $16.0 million pursuant to the manufacturing services agreement, or Jabil MSA, with Jabil Inc., or Jabil , and technical services agreement with Jabil, or Jabil TSA, through January 31, 2021. Under the Jabil MSA, we are obligated to provide, on a monthly basis, a rolling 12-month forecast to Jabil as well as 12-months of historical aggregate end customer demand at the finished product level, when available, which will be used to constitute written purchase orders from us, and we are obligated to purchase the quantity of products that is required by the first four months of each forecast.

We also enter into contracts in the normal course of business with various vendors that generally provide for contract termination following a certain notice period. These contracts do not contain any minimum purchase commitments. Payments due upon cancellation consist only of payments for services provided, expenses incurred up to the date of cancellation and de minimis termination penalties.

We expect that our near and longer-term liquidity requirements will continue to consist of working capital and general corporate expenses associated with the growth of our business. Based on our current planned operations, we expect that our existing cash will enable us to fund our operating expenses for at least 12 months from the date of this filing. 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 would use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, which may not be available to us on acceptable terms, or at all. Furthermore, we may elect to raise additional capital on an opportunistic basis to fund operations. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We may raise additional capital through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or test kits or grant licenses on terms that may not be favorable to us.

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

Cash Flows

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

	For the Six Months Ended June 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (47,622)	$ (5,238)
Investing activities	(8,977)	(2,285)
Financing activities	160,049	23,231
Increase in cash and restricted cash equivalents	103,450	15,708

Cash Flows Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2021 was $47.6 million, consisting primarily of our net loss of $29.5 million and changes in our net operating assets and liabilities of $21.2 million, partially offset by adjustments for non-cash charges of $3.1 million. The non-cash charges were primarily driven by $1.5 million in stock-based compensation expense, $0.9 million in depreciation and amortization, $0.3 million of allowance for doubtful accounts, $0.2 million in noncash lease expense and the loss incurred of $0.3 million on the remeasurement to fair value of the 2020B Notes. The net cash used by changes in our operating assets and liabilities were primarily driven by $31.3 million of inventory purchases, $8.8 million of prepaid expenses, partially offset by $19.2 million increases in accounts payable, accrued liabilities, and customer deposits. The increases in accounts payable and accrued liabilities were largely due to increased expenditures in operations, research and development and selling, general and administrative activities.

Net cash used in operating activities for the six months ended June 30, 2020 was $5.2 million, consisting primarily of our net loss of $8.4 million and changes in our net operating assets and liabilities of $1.3 million, offset by adjustments for non-cash charges of $1.8 million. Our non-cash charges resulted primarily from remeasurement of convertible notes of $1.4 million, stock-

based compensation of $0.1 million, reductions in our right-of-use assets of $0.2 million and depreciation of $0.1 million. Net cash used by changes in our operating assets and liabilities of $1.3 million resulted largely from an increase of $1.6 million in grant income receivable, an increase of $0.6 million in accounts payable and accrued liabilities, partially offset by decrease in prepaid expenses and operating lease liabilities of $0.9 million.

Cash Flows Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 and June 30, 2020 was $9.0 million and $2.3 million, respectively, consisting of purchases of property and equipment. The increase was primarily due to investing in our manufacturing capabilities to support the commercialization of our COVID-19 test kit.

Cash Flows Provided by Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2021 was $160.0 million, consisting primarily of $160.0 million in proceeds from the issuance and sale of shares of our common stock as part of our IPO on February 9, 2021.

Net cash provided by financing activities during the six months ended June 30, 2020 was $23.2 million, consisting primarily of $17.5 million in net proceeds from the issuance redeemable convertible preferred stock and $5.6 million from the issuance of notes payable.

Recently Issued and Adopted Accounting Standards

See Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

Emerging Growth Company Status

The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (1) are no longer an emerging growth company or (2) 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.

We will remain an emerging growth company until the earlier of (1) (a) December 31, 2026, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion or (c) the date on which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item 3.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act refers to controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship

of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. There are currently no material claims, actions or proceedings pending against us or our assets, the ultimate disposition of which we believe could have an adverse effect on our results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

You should carefully consider the following risk factors, together with all other information in this report, including our condensed financial statements and notes thereto, and in our other filings with the Securities and Exchange Commission. If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company. These risks include, but are not limited to, the following:

- We have incurred losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.
- We have refocused our near-term business strategy on responding to the COVID-19 pandemic, for which the diagnostic testing market is new and rapidly developing, making it difficult to evaluate our business and future prospects. Our focus on a new and rapidly developing market could make it difficult to succeed and achieve our goals and could harm our future business prospects.
- We recently received EUAs from the Food and Drug Administration, or FDA, for our COVID-19 test kit. If the FDA revokes or terminates our EUA applications after issuance, such as when the federally-declared COVID-19 public health emergency ends, we will be required to stop commercial distribution of our COVID-19 test kit immediately unless we can obtain FDA clearance for our COVID-19 test kit under a traditional regulatory pathway, which is lengthy and expensive, which could harm our future business prospects.
- The accuracy of our COVID-19 test kit could be impacted by novel strains of SARS-CoV-2 with genetic variations from viral mutation over time. Our COVID-19 test kit may not be successful in detecting future variant strains, which could significantly impact the accuracy and usefulness of our test kit and materially harm our business and prospects.
- The production and widely administered use of an efficacious vaccine or other treatment for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow.
- We are allocating most of our resources to the development, manufacturing and commercialization of our COVID-19 test kit for the foreseeable future, and our long-term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for influenza.
- Our results of operations will be harmed if we are unable to accurately forecast and meet customer and user demand for our test kits and manage our inventory.

- Our near-term success is highly dependent on the successful commercialization of our COVID-19 test kit, and it may not attain or maintain market acceptance or be successfully commercialized in the United States, which could negatively impact our business.

- We are an early-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. If we do not successfully manage the development and launch of our COVID-19 test kit and any future test kits, our financial results could be adversely affected.

- We rely substantially on Jabil for the manufacturing, quality-testing and assembly of our COVID-19 test kit. Any termination or loss of significant rights under the Jabil MSA would harm our commercialization of our COVID-19 test kit. In addition, Jabil may fail to obtain and maintain regulatory approval for its facilities, fail to provide us with sufficient quantities of our COVID-19 test kit or fail to do so at acceptable quality levels or prices.

- The diagnostic testing market, particularly with respect to COVID-19 diagnostic tests, is highly competitive, and many of our competitors are larger, better established and have greater technical and marketing capabilities and financial and other resources than we have.

- The results of our earlier research and development and clinical trials for our influenza test kit may not be replicable in an influenza test kit or in a combination COVID-19 and influenza test kit and may not be sufficient to support FDA approval.

- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

- We may be unable to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for our test kits.

- We have a history of recurring losses and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it.

- We depend on intellectual property licensed from Eiken Chemical Co., Ltd., or Eiken, and the termination of our license could result in the loss of significant rights, which would harm our business.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2020.

Risks Related to Our Business and Strategy

We have incurred losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future, which could harm our future business prospects.

We have incurred net losses since our inception. For the three months and six months ended June 30, 2021, we incurred a net loss of $16.2 million and $29.5 million, respectively, compared to $6.6 million and $8.4 million, respectively, for the same periods in 2020. We expect to incur additional losses and increased operating expenses in future periods. As of June 30, 2021, we had an accumulated deficit of $93.2 million. To date, we have financed our operations principally from issuance and sale of our common stock through our recent initial public offering, grant revenue and the issuances and sales of convertible promissory notes and preferred stock. We have primarily devoted our resources to the research, development, manufacturing and commercialization of our COVID-19 test kit and our influenza test kit, and to research and development activities related to these test kits, including clinical, regulatory and manufacturing initiatives to obtain marketing approval. These losses have, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development, manufacturing, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would make it difficult to finance our business and accomplish our strategic objectives, which would negatively affect our business, financial condition, results of operations, and cash flows.

We have refocused our near-term business strategy on responding to the COVID-19 pandemic, for which the diagnostic testing market is new and rapidly developing, making it difficult to evaluate our business and future prospects. Our focus on a new and rapidly developing market could make it difficult to succeed and achieve our goals and could harm our future business prospects.

Prior to the COVID-19 pandemic, we focused our research and development efforts on developing our molecular nucleic acid amplification technology for use in our influenza test kit. However, based on our clinical trials of our influenza test kit to date, we believe our molecular nucleic acid amplification technology is adaptable to detecting whether a person is shedding the SARS-CoV-2 virus that causes COVID-19. Although we plan to continue our development efforts of our influenza test kit, we have refocused our near-term business strategy to respond to the COVID-19 pandemic. The market for COVID-19 diagnostic testing is new and rapidly developing, which makes it difficult to evaluate our future business prospects and, therefore, we may not be able to achieve our goals and strategy.

We have encountered, and will continue to encounter, risks and difficulties, some of which are outside of our control, frequently experienced in rapidly changing industries, including those related to:

- our ability to compete with companies that are currently in, or may in the future enter, the COVID-19 diagnostic testing market, including companies with greater financial, technical and other resources than our company;
- the possibility that the FDA or similar foreign agency revokes our existing EUAs or similar foreign authorization for our COVID-19 test kit;
- our ability to scale manufacturing to quantities sufficient to meet demand in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements;
- our ability to control costs, including our operating expenses;
- the amount and timing of operating expenses, particularly manufacturing expenses, related to the expansion of our business, operations and infrastructure;
- unanticipated delays in test kit development or test kit launches;
- positive or negative media coverage, or public, user, healthcare provider and/or physician perception, of our COVID-19 test kit or competing products;
- lack or perceived lack of sufficient clinical evidence supporting the accuracy or cost-effectiveness of our COVID-19 test kit over existing products;
- the failure of physicians to prescribe our COVID-19 test kit;
- the failure of third-party payors to cover or adequately reimburse our COVID-19 test kit for prescription at-home and non-laboratory use;
- our ability to meet customer and user demand for our COVID-19 test kit;
- our ability to achieve or maintain a consumer-appropriate retail price;
- our ability to obtain, maintain and enforce our intellectual property rights; and
- general economic and political conditions.

Given the unpredictable nature of the COVID-19 pandemic, the potential size of the COVID-19 diagnostic testing market and the timing of its development are highly uncertain. In addition, the production and widely administered use of an efficacious vaccine or treatment for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow. Currently there are companies developing vaccines and therapeutic treatments for COVID-19, and from December 2020 through February 2021, the FDA issued EUAs for three COVID-19 vaccines. Our future success is substantially dependent on the manner in which the market for COVID-19 diagnostic testing develops and grows. If the

market develops in a manner that does not facilitate demand for our COVID-19 test kit, or fails to develop or grow in the manner in which we expect or at all, our business, financial condition, results of operations and cash flows may be negatively affected.

We recently received EUAs from the FDA for our COVID-19 test kit. If the FDA revokes or terminates our EUA applications after issuance, such as when the federally-declared COVID-19 public health emergency ends, we will be required to stop commercial distribution of our COVID-19 test kit immediately unless we can obtain FDA clearance for our COVID-19 test kit under a traditional regulatory pathway, which is lengthy and expensive, which could harm our future business prospects.*

Under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the FDA has authority to allow certain unapproved medical products or unapproved uses of approved 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. In issuing an EUA, the FDA will consider the totality of scientific evidence available to the FDA regarding safety, efficacy and known and potential risks of such products and availability of alternatives to the emergency use products, among others. EUAs issued by the FDA specify the scope of authorization and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. Once granted, an EUA is effective until the declaration that circumstances justifying the authorization of the emergency use is terminated or the EUA is revoked, after which the product must be approved by the FDA under a traditional pathway in order to remain on the market or to continue commercialization of the product.

On November 17, 2020, we received an EUA from the FDA for POC and prescription at-home indications for the detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19, in nasal swab samples from people who are suspected of COVID-19. We are working towards expanding this indication and submitted an amended EUA application to include detection of nucleic acid from SARS-CoV-2 in asymptomatic people in February 2021. On April 9, 2021, we received an EUA from the FDA for our COVID-19 test kit for OTC non-prescription use among symptomatic and asymptomatic individuals aged 14 and older (with self-collection) and children aged two to 13 (with parent collection). The FDA may require additional data, including additional validation data and clinical performance data, and may not ultimately issue an authorization to expand our POC indication. Changes in FDA policies, guidance, and requirements for EUA application submission may delay FDA authorization of additional indications for our COVID-19 test kit. Further, given the high volume of EUA requests received by the FDA and other factors due to the COVID-19 pandemic, including any disruptions in the FDA's normal operations, the FDA's review of an amended or additional EUA application may be significantly delayed. The FDA may not grant an EUA for additional indications of our COVID-19 test kit on a timely basis or at all, which could harm our future business prospects. On June 30, 2021, we withdrew our pending EUA application with the FDA that was intended to expand our current prescription EUA for suspected symptomatic individuals to include asymptomatic individuals because we decided instead to refocus on an FDA 510(k) submission.

The distribution and advertising conditions set forth in our existing EUAs limit our market opportunities and restrict how we can commercialize our COVID-19 test kit. For example, according to our authorized EUAs, our COVID-19 test kit must comply with certain labeling requirements, including the label that our COVID-19 test kit has not been FDA cleared or approved but has been authorized by the FDA under an EUA and that our COVID-19 test kit has been authorized only for the detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens. In addition, if any additional EUAs are granted for our COVID-19 test kit, the distribution and advertising conditions set forth in the EUA may limit our market opportunities or restrict how we can commercialize our COVID-19 test kit. If the FDA's policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our COVID-19 test kit could be adversely impacted. In addition, the FDA may revoke our existing or any future EUA where it is determined that the COVID-19 public health emergency no longer exists or warrants such authorization, or if new evidence becomes available that indicates that our test kit is not as safe, effective or reliable as the data provided in the applicable EUA application. We cannot predict how long an EUA will remain effective and we may not receive advance notice from the FDA regarding revocation of our EUAs. The termination or revocation of our existing EUAs for our COVID-19 test kit would cause us to cease our commercialization efforts until and if 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 kit, which could limit, delay or prevent commercialization of our COVID-19 test kit and could adversely impact our business, financial condition and results of operations.

We are allocating most of our resources to the development, manufacturing and commercialization of our COVID-19 test kit for the foreseeable future, and our long-term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for influenza.

We are committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of our COVID-19 test kit. For example, on September 10, 2020, we entered into the Jabil MSA to support the commercial manufacturing of our COVID-19 test kit and on November 17, 2020, we received our first EUA from the FDA for POC and prescription at-home indications for the detection of nucleic acid from SARS-CoV-2, the virus that causes COVID-19, in nasal swab samples from people who are suspected of COVID-19. Our business could be negatively impacted by our allocation of

significant resources to a global health threat that is unpredictable and could dissipate or stabilize, which would limit or eliminate demand for our COVID-19 test kit. We may not be able to successfully commence or recommence the development, manufacturing and commercialization of our influenza test kit that remains under development.

Our near-term success is highly dependent on the successful commercialization of our COVID-19 test kit, and it may not attain or maintain market acceptance or be successfully commercialized in the United States, which could negatively impact our business.*

Our near-term prospects, including our ability to finance our company and generate revenue, as well as our future growth, is highly dependent on the successful and timely regulatory approval from the FDA and commercialization of our COVID-19 test kit. The regulatory and commercial success of our COVID-19 test kit will depend on a number of factors, some of which are outside our control, including the following:

- whether we are required by the FDA or other similar regulatory authorities to conduct additional clinical trials or to modify the design of our current trials to support the approval of our COVID-19 test kit;
- achieving and maintaining compliance with all regulatory requirements applicable to our COVID-19 test kit;
- the acceptance by the medical community and others of the convenience and accuracy of our COVID-19 test kit and the sufficiency of clinical evidence supporting our COVID-19 test kit;
- the ability of our COVID-19 test kit to accurately detect different strains of SARS-CoV-2, created by genetic mutation or otherwise, such as the five notable SARS-CoV-2 variants in the U.K., South Africa, Brazil and two California and the spike double mutant detected in India and California;
- our ability to obtain coverage and adequate reimbursement from third-party payors for prescription at-home use of our COVID-19 test kit; and
- the ability of Jabil and other third parties with whom we may contract to manufacture our COVID-19 test kit to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with applicable requirements and to manufacture sufficient quantities of our test kits to meet demand in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements.

Even though we have received EUAs for our COVID-19 test kit, it may not gain broad market acceptance among our customers, including physicians, healthcare payors, users and others in the medical community. The commercial success of our COVID-19 test kit will initially be dependent upon physicians and healthcare providers adopting our test kit, which will be informed, in part, by the convenience and accuracy of our COVID-19 test kit. The accuracy of our COVID-19 test kit could be impacted by novel strains of SARS-CoV-2 with genetic variations from viral mutation over time.

The CDC has highlighted the emergence of four notable SARS-CoV-2 variants of concern: Alpha (also known as B.1.1.7) first detected in the U.K., Beta (also known as B.1.351, B.1.351.2, B.1.351.3) first detected in South Africa, Delta (also known as B.1.617.2,AY.1, AY.2, AY.3) first detected in India and Gamma (also known as P.1, P.1.1, P.1.2) first detected in Japan/Brazil. Additionally, two variants of Interest have been identified to be rising in prevalence: Lambda (also known as C.37) first detected in Peru and B.1.621 first detected in Columbia. We perform routine surveillance of emerging SARS-CoV-2 strains by periodically evaluating in silico reactivity against sequence databases. These evaluations have shown that these variants are reactive to our COVID-19 test kit. Our assay targets two non-overlapping regions of the N gene. Hence the detection region is unaffected by the mutations of the spike protein of SARS-CoV-2 in the variant strains. As these particular viral strains become commercially available for testing, we intend to perform testing to confirm detection with these strains.

Moreover, our COVID-19 test kit is authorized under EUAs from the FDA for the detection of the novel coronavirus SARS-CoV-2 that causes COVID-19, regardless of the virus variant. The FDA may require us to conduct additional clinical trials or seek a new or amended EUA and our COVID-19 test kit may not be successful in detecting future variant strains, which could significantly impact the accuracy and usefulness of our test kit and materially harm our business and prospects. In addition, the risk of false negative results may increase when testing patients with genetic variants of SARS-CoV-2, including the four notable SARS-CoV-2 variants.

In addition, the COVID-19 diagnostic testing market is susceptible to rapid technological developments and we may not be able to match any new technological advances, which would render our COVID-19 test kit uncompetitive or obsolete, even if it were to gain widespread market acceptance initially. If we are unable to match technological improvements in competitive products or effectively respond to the needs of our customers and users, the demand for our COVID-19 test kit could be reduced.

Our commercial success, including acceptance and use of our COVID-19 test kit, will depend upon a number of factors, some of which are beyond our control, including:

- the timely receipt of additional marketing authorizations and approvals from the FDA and other similar regulatory authorities;
- perceptions by the public and members of the medical community, including physicians, as to its convenience, accuracy and the sufficiency of clinical evidence supporting its performance;
- demand from the public and members of the medical community for our COVID-19 test kit and adoption of our test kit;
- the availability, perceived advantages, relative cost, relative convenience and relative accuracy of our COVID-19 test kit compared to those of our competitors;
- positive or negative media coverage of our COVID-19 test kit 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, including our ability to have a sufficient number of talented sales representatives to sell our test kits and the success of our direct-to-consumer marketing efforts;
- unanticipated delays in manufacturing, test kit development or test kit launch;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our COVID-19 test kit;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our COVID-19 test kit;
- our ability to obtain, maintain and enforce our intellectual property rights;
- our ability to maintain a continued supply of test kit materials that meets our quality control requirements;
- the ability of Jabil and other third parties with whom we may contract to manufacture our COVID-19 test kit to manufacture and supply sufficient quantities of our COVID-19 test kit to meet demand in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements;
- limitation on use or warnings required by the FDA in our COVID-19 test kit labeling; and
- availability of, or changes in, coverage or reimbursement rates for our COVID-19 test kit from government or other commercial or healthcare payors.

Our future success also depends upon consumers having an experience with our COVID-19 test kit that meets their expectations in order to increase demand for our COVID-19 test kit as a result of positive feedback and word-of-mouth. Consumers may be dissatisfied if their expectations of the diagnostic test and results are not met. Consumers may also be dissatisfied if they experience adverse events, such as device malfunctions, inaccurate readouts or significantly delayed responses. If our COVID-19 test kit does not meet the expectations of consumers, or if consumers experience adverse events, it could discourage consumers from repurchasing our COVID-19 test kit or referring our COVID-19 test kit to others. Further, dissatisfied consumers may express negative opinions through social media. Any failure to meet consumer expectations and any resulting negative publicity could harm our reputation and future sales.

Our near-term revenue will be primarily generated from sales of our COVID-19 test kit, and we are highly dependent on it for our success.

We expect that sales of our COVID-19 test kit will account for the substantial majority of our revenue for the foreseeable future. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption of our COVID-19 test kit by consumers. We currently only have a very small number of existing customers and customers with whom we are actively negotiating contracts. We may not be able to successfully negotiate additional customer contracts in a timely manner, on terms favorable to us or at all. If we are unable to execute additional contracts and expand our customer base, we will not be able to increase our revenues which will have a material adverse impact on our business and results of operation. This risk is particularly exacerbated given our very early stage of commercial operations and limited experience with selling and commercializing our products and negotiating contracts with potential customers. We may not be successful in expanding our customer base significantly, or at all. Adoption and use of our COVID-19 test kit will depend on several factors, including, but not limited to the accuracy, affordability and ease of use of our test kit as compared to existing products, and coverage and reimbursement policies with respect to our COVID-19 test kit and products that compete with our COVID-19 test kit. Our COVID-19 test kit may not gain market acceptance, and any failure to do so would harm our business and results of operations.

Because we expect virtually all of our revenue for the foreseeable future to be generated from sales of our COVID-19 test kit, the failure of our COVID-19 test kit to garner market acceptance would substantially harm our business and would adversely affect our revenue. If our COVID-19 test kit is not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of our COVID-19 test kit to be successfully commercialized may have a material adverse effect on our business, operating results, financial condition and cash flows, and could result in a substantial decline in the price of our common stock.

If we are unable to expand our marketing infrastructure, we may fail to increase customer adoption of our test kits to meet our forecasts.*

We launched direct-to-consumer sales through our website after we received an EUA from the FDA for OTC use of our COVID-19 test kit in April 2021. Additionally, our COVID-19 test kit was made available on Amazon.com in May 2021. As a result, we have only limited experience marketing our offerings and engaging customers at our current scale. We plan to derive a meaningful portion of our revenue from consumer purchases of our COVID-19 test kit. Our ability to expand direct-to-consumer sales and drive broad customer adoption of our test kits is integral to our business. Our financial condition and results of operations are and will continue to be highly dependent on the ability of our marketing function to adequately promote, market, and attract customers to our test kits in a manner that complies with applicable laws and regulations.

A key element of our business strategy is the continued expansion of our marketing infrastructure and building brand awareness. As we increase our marketing efforts in connection with the expansion of our OTC COVID-19 test kit sales, we will need to further expand the reach of our marketing networks. Our future success will depend largely on our ability to continue to hire, train, retain, and motivate a skilled marketing workforce with significant industry-specific knowledge in various areas, including direct-to-consumer business models, e-commerce, technology, healthcare, and the regulatory restrictions related thereto, as well as the competitive landscape for our test kits.

If we are unable to expand our marketing capabilities, we may not be able to effectively attract customers. Relatedly, if any of our marketing platforms significantly increase their advertising fees, our ability to expand our marketing reach will be greatly impeded. Any such failure could adversely affect our reputation, revenue, and results of operations.

Direct-to-consumer marketing and social media efforts may expose us to additional regulatory scrutiny, including from the Federal Trade Commission, or FTC, and other consumer protection agencies and regulators*.

In addition to the laws and regulations enforced by the FDA, advertising for non-restricted medical devices is subject to federal truth-in-advertising laws enforced by the FTC, as well as comparable state consumer protection laws. Our efforts to promote our prescription and OTC test kits via direct-to-consumer marketing and social media initiatives may subject us to additional scrutiny of our practices. For example, the FTC and other consumer protection agencies scrutinize all forms of advertising (whether in digital or traditional formats) for consumer-directed products and non-restricted medical devices to ensure that advertisers are not making

false, misleading or unsubstantiated claims or failing to disclose material relationships between the advertiser and its products' endorsers, among other potential issues.

Under the Federal Trade Commission Act, or FTC Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution. We plan to increase our advertising activities that may be subject to these federal and state truth-in-advertising laws. Any actual or perceived non-compliance with those laws could lead to an investigation by the FTC or a comparable state agency, or could lead to allegations of misleading advertising by private plaintiffs. Any such action against us would disrupt our business operations, cause damage to our reputation, and result in a material adverse effect on our business.

We are an early-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. If we do not successfully manage the development and launch of our COVID-19 test kit and any future test kits, our financial results could be adversely affected.

We are an early-stage company and have a limited operating history. We began our operations in 2013 and we commercially launched our COVID-19 test kit in the first quarter of 2021 in the United States in accordance with our POC and prescription at-home indications. Our limited commercial operating history may make it difficult to evaluate our current business and predict our future performance. Any assessment of our profitability or prediction about our future success or viability is subject to significant uncertainty. We have encountered and will continue to encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving industries. If we do not address these risks successfully, it could have a material adverse effect on our revenue, results of operations and business.

In addition, we face risks associated with launching new test kits, such as our COVID-19 test kit. Additionally, as an organization, we have not yet demonstrated an ability to successfully manufacture a commercial scale test kit or conduct sales and marketing activities necessary for successful commercialization. If we encounter development or manufacturing challenges or discover errors during our product development cycle, the product launch dates of our COVID-19 test kit and any future test kits may be delayed. The expenses or losses associated with unsuccessful product development or launch activities or lack of market acceptance of our new test kits could adversely affect our business or financial condition.

We rely substantially on Jabil for the manufacturing, quality-testing and assembly of our COVID-19 test kit. Any termination or loss of significant rights under the Jabil MSA would harm our commercialization of our COVID-19 test kit. In addition, Jabil may fail to obtain and maintain regulatory approval for its facilities, fail to provide us with sufficient quantities of our COVID-19 test kit or fail to do so at acceptable quality levels or prices.*

We rely substantially and intend to continue to rely substantially on Jabil for the manufacturing, quality-testing and assembly of our COVID-19 test kit. Pursuant to the Jabil MSA, Jabil has agreed to manufacture, test, pack and ship our COVID-19 test kit in accordance with our specifications and applicable forecasts and purchase orders. We are obligated to provide, on a monthly basis, a rolling 12-month forecast to Jabil of historical aggregate end customer demand at the finished product level, which will be used to constitute written purchase orders. After the initial term of three years, the Jabil MSA renews automatically for consecutive one-year terms, subject to written notice of the intention not to renew from either party, given at least 180 days prior to the expiration of the then-current yearly term. The parties may terminate the Jabil MSA at any time upon mutual written consent, and either party may terminate the Jabil MSA upon 180 days prior written notice. Either party may also terminate the Jabil MSA upon a material breach by the other party that is not cured within 30 days after receiving written notice of the breach, or upon a bankruptcy of the other party.

Any termination or loss of rights under the Jabil MSA would harm our ability to commercialize, sell and distribute our COVID-19 test kit, which in turn would have a material adverse effect on our business, operating results and prospects. If we were to lose our rights under the Jabil MSA, we believe it would be difficult for us to find an alternative manufacturer. In addition, to the extent Jabil or the alternative manufacturer has not secured applicable regulatory approvals, we would have to expend significant resources to obtain regulatory approvals that may never be obtained or require several years to obtain, which could significantly delay commercialization. We may be unable to raise additional capital to fund our operations during this extended time on terms acceptable to us or at all. In addition, if we were to commercialize our COVID-19 test kit and later experience manufacturing delays as a result of a dispute with Jabil or otherwise, the supply of our COVID-19 test kit could be harmed.

In addition, the manufacture of medical devices is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. As Jabil has not yet operated assembly lines for our products at scale, it may be difficult to predict the cost of manufacturing our test kits. We may not be able to manufacture our test kits at expected prices. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our test kits, changes to labor costs or less favorable terms with third-party suppliers or contract manufacturing partners. As a result, even if automated production lines perform as anticipated, it may not be possible to manufacture our products in a profitable manner.

Manufacturers of medical devices encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We are currently working with Jabil to increase manufacturing production and capacity at its facilities located in Michigan and the Dominican Republic. In order to achieve our near-term and long-term operational and financial plans, we need to substantially increase the manufacturing capacity to which we have access, and there is no assurance that we would be able to do so in a timely manner, or at all. If Jabil is unable to increase and achieve our required or target production capacities, we would be unable to fulfill our actual or anticipated customer demand which would negatively impact our business, financial condition and results of operations. In addition, our inability to meet the 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. Any issues relating to the manufacture of our test kits, including with respect to scaling up and validating initial production, may occur in the future. These risks could be exacerbated by Jabil's limited experience with our COVID-19 test kit and related manufacturing processes.

In addition, quarantines, shelter-in-place and similar government orders related to COVID-19 or other infectious diseases, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact personnel at Jabil's facilities upon which we rely. Further, Jabil may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If Jabil were to encounter any of these difficulties, or otherwise fail to comply with its contractual obligations, our ability to commercialize our COVID-19 test kit would be jeopardized.

The diagnostic testing market, particularly with respect to COVID-19 diagnostic tests, is highly competitive, and many of our competitors are larger, better established and have greater technical and marketing capabilities and financial and other resources than we have. In addition, we expect competition with respect to testing solutions for COVID-19 to continue to increase and our success will depend on widespread market acceptance of our COVID-19 test kit.*

The diagnostic testing market, particularly with respect to COVID-19 diagnostic tests, is highly competitive and we face substantial competition based on factors such as product quality, underlying technology, analytical performance, accuracy, speed of results, convenience and ease of use, price, product enhancements, customer and user service and reputation. Industry competition is also based the following additional factors, among others:

- patent protection;
- evidence of clinical performance and support of KOLs;
- scientific expertise;
- ability to develop and market products and processes and meet consumer demand;
- ability to obtain and maintain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- pricing and reimbursement levels;
- access to adequate capital; and
- ability to attract and retain qualified personnel.

In diagnostic testing, we anticipate facing competition from companies that have or are developing molecular tests (including centralized laboratory and POC tests) as well as antigen and antibody tests. Antigen tests in particular are a source of

competition because they are rapid and are already in use across the United States for mass-population testing. We will also compete on the basis of test methods, such as tests that utilize nasopharyngeal and mid-turbinate swab collection methods, saliva collection methods as well as other methods that may be developed in the future.

We face potential competition from many sources, including academic institutions, public and private research institutions and governmental agencies. Competitors with COVID-19 diagnostic testing platforms currently include, but are not limited to, private and public companies, such as Abbott Laboratories, Inc., or Abbott, Cue, Danaher Corp., Bio-Rad Laboratories, F. Hoffman-La Roche Ltd., Becton, Dickinson and Company, or BD, Thermo Fisher Scientific, Inc., Siemens AG, BioMerieux SA, GenMark Diagnostics Inc., Qiagen, Sherlock Biosciences, Mammoth Biosciences, Everlywell, Inc., the CDC, Mesa Biotech, Inc., Quidel Corporation, Talis Biomedical Corporation, Visby Medical, Ginkgo Bioworks, Helix OpCo, LLC and Fluidigm Corporation. Large lab companies like Quest Diagnostics, Inc. and Laboratory Corporation of America have also expanded beyond centralized laboratory testing into home sample collection.

We could see a significant reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are faster, more convenient or are less expensive than our COVID-19 test kit or any other test kits that we may develop. Our competitors also may be quicker and/or more successful than us in obtaining FDA or other regulatory approvals for their products, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for our COVID-19 test kit. Many of those competitors are significantly larger, and have substantially greater financial, scientific, manufacturing and other resources, than us. 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. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater functionality or at lower cost than ours. In July of 2020, BD announced FDA approval of its EUA application for the BD Veritor System for Rapid Detection of SARS-CoV-2. This test is a chromatographic immunoassay for the direct and qualitative detection of SARS-CoV-2 antigens in nasal swabs from patients with signs and symptoms who are suspected of COVID-19. In August 2020, Abbott announced FDA approval of its POC EUA application for BinaxNOW COVID-19 Ag Card, Abbott's COVID-19 antigen test. In December 2020, the FDA updated the Abbott BinaxNOW COVID-19 Ag Card antigen test to include prescription at-home use among people suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset; this test may only be performed when supervised by a telehealth proctor. In March 2021, the FDA issued an EUA to Quidel for its QuickVue COVID-19 antigen test to be used in the prescription at-home setting among people suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. The FDA also granted an EUA to the Ellume COVID-19 Home Test, an OTC antigen test, Abbott's BinaxNOW, an OTC antigen test, and to Cue for its molecular OTC COVID-19 test.

If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. The success or failure, or perceived success or failure, of other companies may adversely impact our ability to obtain any future funding, or to ultimately commercialize our COVID-19 test kit.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. For example, Abbott introduced a mobile phone application to allow people to display the results of their COVID-19 test obtained through a healthcare provider when entering facilities requiring proof of testing. Moreover, the entrance of new competitors is being encouraged by governmental authorities, which are offering significant funding to support development of testing solutions for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer and user requirements. Our COVID-19 test kit may not compete favorably, and we may not be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. Any failure to compete effectively could harm our business, financial condition and operating results.

The production and widely administered use of an efficacious vaccine or treatment for COVID-19 may reduce the demand for diagnostic tests and, as a result, the COVID-19 diagnostic testing market may not develop or substantially grow.

Currently, there are companies developing vaccines and therapeutic treatments for COVID-19. From December 2020 through February 2021, the FDA issued EUAs for three COVID-19 vaccines, which are currently being administered in the United States, the U.K. and other countries. If current or future vaccines are widely distributed and compliantly administered, or if new therapeutic treatments are identified and become widely used, then our testing opportunities and market interest may lessen or disappear. Our future success is substantially dependent on the manner in which the market for COVID-19 diagnostic testing develops and grows. If the market develops in a manner that does not facilitate demand for our COVID-19 test kit, or fails to develop or grow in

the manner in which we expect or at all, our business, financial condition, results of operations and cash flows may be negatively affected.

We rely on a limited number of suppliers or, in many cases, a single supplier, for test kit materials and may not be able to find replacements or immediately transition to alternative suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

We have sourced and will continue to source test kit components, molds, reagents and other test kit materials from a limited number of suppliers or, in many cases, a single supplier. For example, our molds and many of our reagents are sole-sourced. In addition, we rely solely on Promega Corporation and New England BioLabs, Inc. for the supply of our current enzymes and primers. We intend to put in place framework agreements with certain of our single-source suppliers, including Promega Corporation and New England BioLabs, Inc., under which these third-party contract suppliers will generally provide us with necessary quantities of such materials based on our development and commercial needs. However, we may be unsuccessful in putting in place such framework agreements on acceptable terms or at all, or in otherwise protecting against potential supply disruptions. Our failure to maintain a continued supply of these test kit materials would adversely impact our business, financial condition and results of operations.

Because we rely on third-party suppliers, we do not control the manufacture of the components of our test kits, including whether such components will meet our quality control requirements, nor the compliance of our suppliers with applicable legal and regulatory requirements. In many cases, our suppliers are not contractually required to supply these components to the quality or performance standards that we require. If the supply of components we receive does not meet our quality control or performance standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, which occasionally occurs with respect to certain reagents our tests may not work properly or at all, or they may provide erroneous results, and we may be subject to significant delays caused by interruption in production or manufacturing, to lost revenue from such interruption or from spoiled tests, or to the effects of negative perception related to defective test kits.

In the event that any adverse developments occur with our suppliers, in particular for those products that are sole-sourced, or if any of our suppliers modifies any of the components they supply to us, our ability to supply our test kits may be temporarily or permanently interrupted. Obtaining substitute components could be difficult, time and resource-consuming and costly or it could require us to re-design or re-validate our test kits. Our failure to maintain a continued supply of components that meets our quality control requirements for any reason, including changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers, particularly in the case of sole suppliers, could result in the loss of access to important materials of our test kits and impact our test performance or affect our ability to supply fully functional test kits in a timely manner or at all, which could impair, delay or suspend our commercialization activities.

Moreover, in the event that we transition to a new supplier from any of our sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our test kits to the market, could affect the performance of our test kits or could require that we re-validate our processes and our other test kits using replacement equipment and supplies, which could hinder the adoption of our test kits, resulting in increased costs and negative customer and/or user perception. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at our suppliers upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our test kits. Any delay or interruption in the supply of our test kit materials could delay or suspend the commercialization of our test kits and increase the costs of manufacturing our test kits, which could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to an order from federal or state governments, including pursuant to the Defense Production Act of 1950, as amended, or the DPA, to distribute our COVID-19 test kit directly to the government or as directed by the government, which could adversely affect our business, financial condition and results of operations.

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, the President of the United States has used this authority more than 30 times to address the public health crisis. Through the DPA, the executive branch has struck agreements with multiple companies to accelerate COVID-19 countermeasures, like producing N95 protective masks, testing swabs, and vaccine development, and, in September 2020, used the DPA to acquire POC diagnostic testing instruments from two of our potential competitors for placement in nursing homes, and to require one of our potential competitors to prioritize government orders over others. The government may similarly apply the DPA, or

another law or program, to our existing or potential new contracts to acquire our COVID-19 test kits 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 instruments 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. 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 the recent change in the 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 results of our earlier research and development and clinical trials for our influenza test kit may not be replicable in an influenza test kit or in a combination COVID-19 and influenza test kit and may not be sufficient to support the authorization of an influenza test kit or a combination COVID-19 and influenza test kit.

Since inception, we have primarily focused on the research and development of our influenza test kit. We conducted two clinical trials in 2018 and 2019 for our influenza test kit in Santiago, Chile, and the United States. The clinical trial conducted in the United States served as the basis for our dual 510(k) and Clinical Laboratory Improvements Amendment, or CLIA, waiver submission for our influenza test kit in the second half of 2019. This clinical trial was conducted across the 2018 and 2019 influenza season and included a comparator. This clinical trial showed similarly strong assay performance as the initial Chile clinical trial, but we failed to meet required endpoints as a result of two main issues. First, the comparator did not detect influenza A virus as well as our assay did, which negatively and artificially lowered our influenza A virus specificity to 92% in the clinical trial. When applying discrepant resolution, our influenza A virus specificity improved to 97%. The impact of running this clinical trial with a single comparator and the comparator not correctly identifying at least 35 specimens as true positives impeded us from being able to provide the necessary clinical data with the level of specificity required by the FDA without additional clinical testing. The second issue related to a higher than anticipated rate of invalids, at nearly 10%. Root cause analysis showed greater than half of invalids to be related to prototype manufacturing quality issues, and importantly, not related to fundamental assay performance. We believe these issues have since been resolved and the assay's invalid rate is now less than 5%. In January 2020, we received an additional information letter from the FDA discussing this clinical trial and the resulting comparator issues, high rate of invalids and exclusion of samples. As a result, we withdrew our dual 510(k) and CLIA waiver submission for our influenza assay and shifted our focus to the COVID-19 pandemic.

Based on our clinical trials of our influenza test kit to date, we believe our molecular nucleic acid amplification technology is adaptable to detecting whether a person is shedding the influenza A or B viruses that cause influenza. However, the results of our earlier research and development and clinical trials for our influenza test kit may not be replicable in a combination COVID-19 and influenza test kit or sufficient to support the approval of a combination COVID-19 and influenza test kit. Additional clinical trials on the combination COVID-19 and influenza test kit will be required for FDA submission. In addition, the FDA may weigh the results of our prior clinical trials related to our influenza test kit and the issues raised in its January 2020 additional information letter more heavily than anticipated, potentially hindering our future FDA approval of our influenza test kit. We are uncertain as to whether the combined COVID-19 and influenza clinical trials will be successful, and the future trials may not replicate the results of prior clinical trials and pre-clinical studies.

If our test kits fail to achieve the broad degree of adoption by the medical community necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Even if our test kits receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, customers and others in the medical community. The commercial success of our test kits will depend significantly on sufficient coverage and reimbursement by third-party payors, the broad adoption and use of our test kits by physicians and, for OTC use, ultimate users, for authorized or approved indications. We are aware that other companies are seeking to develop alternative diagnostic products for COVID-19 and influenza, any of which could impact the demand for our COVID-19 test kit and our influenza test kit, respectively.

The degree and rate of physician, patient and customer adoption of any of our test kits, and initially our COVID-19 test kit, depend on a number of factors, some of which are beyond our control, including:

- the accuracy, affordability and ease of use of our test kits as compared to existing diagnostic products;
- physician adoption of our combination of LAMP and proprietary colorimetric detection chemistry;
- lack or perceived lack of sufficient clinical evidence supporting the accuracy and performance of our test kits;
- physician and patient willingness to adopt our test kits to treat COVID-19 and influenza over diagnostic products and brands with which patients and physicians may have more familiarity or recognition or additional approved uses;
- any perceived burdens imposed on physicians or patients with respect to public health reporting obligations for certain infectious diseases such as COVID-19;
- overcoming any biases physicians or patients may have toward the accuracy and ease of use of existing diagnostic test kits and successful marketing efforts;
- the cost of our test kits in relation to alternative diagnostic products, and in the OTC setting, patient willingness to pay for our test kits;
- proper training in the use of our test kits by physicians and healthcare providers;
- patient satisfaction with the accuracy and ease of use of our test kits and overall user experience;
- changes in pricing and promotional efforts by competitors;
- coverage and reimbursement policies with respect to our test kits and products that compete with our test kits;
- patient demand for POC and OTC diagnostic testing;
- the revenue and profitability that our test kits may offer a physician as compared to alternative diagnostic tests;
- the effectiveness of our sales, marketing and distribution efforts; and
- adverse publicity about our test kits, competitive products, or the industry as a whole, or favorable publicity about competitive products.

Further, outbreaks of highly contagious diseases, like COVID-19 and influenza, require immediate, mass population testing; however, we believe the traditional testing infrastructure within the United States is not designed to support mass population testing at high-complexity labs or at the POC. Accordingly, the ease of integration of our test kits into a physician's practice may not be as evident as we anticipate.

In addition, our COVID-19 test kit utilizes our combination of LAMP and proprietary colorimetric detection chemistry. Physicians may prefer to use diagnostic tests with alternative technologies, such as PCR, or even antigen or antibody diagnostic tests. If our test kits fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

If we do not have the support of physicians or KOLs, it may be difficult to drive adoption of our test kits, which could limit our revenue growth and our ability to achieve profitability.

Building on our usability studies and EUA indications, we plan to leverage our clinical work to publish key research and articles as a way to increase awareness and drive adoption among users, healthcare providers, physicians and KOLs. If physicians and KOLs in particular determine that our test kits are not accurate or easy to use and bill for, or that alternative diagnostic tests are more accurate or easier to use and bill for, we may see lower demand for our test kits, and face difficulty establishing our test kits as an integral component of the applicable standard of testing, which would limit our revenue growth and our ability to achieve profitability. If our test kits do not receive sufficient favorable exposure in peer-reviewed publications, the rate of physician adoption of our test kits and positive reimbursement coverage determinations for our test kits could be negatively affected.

The initial use of our test kits requires users to follow instructions, and not adhering to instructions may lead to negative outcomes, which could harm our business.

The successful use of our test kits depends on a user following the test instructions. Any user, whether it be a healthcare provider or patient at home, could experience difficulty performing a test using our test kits if they fail to follow the instructions, or otherwise misuse the test. If physicians or other users utilize our test kits incorrectly, or without adhering to our instructions, their test result outcomes may not be consistent with the outcomes achieved in our clinical trials. This could harm our ability to achieve the broad degree of physician adoption necessary for commercial success, or cause negative publicity and word-of-mouth as a result of our test kits 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.

We may be unable to obtain and maintain adequate levels of coverage and reimbursement from third-party payors for our test kits.

Our market success is dependent upon government and commercial third-party payors providing coverage and adequate reimbursement for our test kits. Under the EUA authorized for the POC setting, our COVID-19 test kit is eligible for reimbursement as a molecular POC test. However, 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, which could adversely affect the market for our COVID-19 test kit. In addition, there is currently no approved coverage for at-home COVID-19 testing in the United States and the reimbursement rate for our at-home test is uncertain. Third-party payors may require additional clinical or other data in order to cover our test kit in certain settings.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

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 approved test kits, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, manufacturing, regulatory approval and commercialization activities relating to our test kits, which may change from time to time;
- the size, seasonality and customer mix of the COVID-19 and influenza diagnostic testing market;
- 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 or clinical publications of our test kits or competitive products;
- the cost of manufacturing our test kits, which may vary depending on the quantity of production and the terms of our arrangements with Jabil and our suppliers;
- the introduction of new test kits or enhancements or technologies by us or others in the diagnostic testing industry;
- pricing pressures;
- coverage and reimbursement policies with respect to our test kits and products that compete with our test kits;
- expenditures that we may incur to acquire, develop or commercialize test kits 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 effects of 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. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

We may not be able to achieve or maintain satisfactory pricing and margins for our 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 satisfactory prices for our test kits. Our POC pricing is at a modest premium to other POC tests and we may not be able to achieve or maintain a consumer-appropriate retail price for OTC use. The pricing of our 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 our test kits. If we are forced to lower the price we may charge for our test kits, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, not purchase our tests in significant volumes or at all, especially in the OTC market, or otherwise in the absence of reimbursement, and our margins could erode. We may be subject to significant pricing pressure, which could harm our business and results of operations.

Our results of operations will be harmed if we are unable to accurately forecast and meet customer and user demand for our test kits and manage our inventory.*

To ensure adequate supply, we must forecast inventory needs and manufacture our test kits based on our estimates of future demand. For example, pursuant to the Jabil MSA, we are obligated to provide, on a monthly basis, a rolling 12-month forecast to Jabil of historical aggregate end customer demand at the finished product level, which will be used to constitute written purchase orders. Our ability to accurately forecast demand for our test kits 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 test kits 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 an efficacious vaccine or treatment for COVID-19, seasonal demands, or regulatory matters and weakening of economic conditions or user confidence in future economic conditions. In addition, we may experience fluctuations in customer and user demand based on seasonality, which for COVID-19, remains unknown. However, for example, because influenza typically occurs in the fall and winter seasons, we expect our forecasts of inventory for these seasons to reflect a significant increase in inventory 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.

Conversely, if we underestimate customer and user demand for our test kits, our manufacturing partner, Jabil, may not be able to deliver test kits that meet our requirements. Demand has exceeded supply for our COVID-19 test kits, and we have temporarily halted online sales, which could result in damage to our reputation and customer relationships. 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. We rely substantially on Jabil to manufacture our COVID-19 test kit initially at manufacturing facilities located in Michigan and in the Dominican Republic. If Jabil is unable to increase and achieve our required or target production capacities, we would be unable fulfill our actual or anticipated customer demand which would negatively impact our business, financial condition and results of operations. In addition, our inability to meet the 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, which 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 depend on intellectual property licensed from Eiken and the termination of our license could result in the loss of significant rights, which would harm our business.

We are dependent on patents licensed from Eiken. In July 2020, we entered into a patent license agreement, or the Eiken Agreement, with Eiken. Pursuant to the terms of the Eiken Agreement, Eiken granted us a non-transferable, non-assignable, sublicensable (solely to our affiliates), non-exclusive license under certain patents, which we refer to collectively as the Eiken Licensed Patents, relating to LAMP and as listed in the Eiken Agreement, to develop and make any reagent, product, kit, device, equipment and/or system for nucleic acid-based in vitro diagnostic, or IVD, tests for detection of SARS-CoV-2, which causes COVID-19, which we collectively refer to as the Initial Licensed Products, in the United States. The Eiken Licensed Patents allow us to use LAMP to amplify genetic material. In addition, we own patents covering the necessary additional step of detection of target genetic material. Eiken may license patents to additional third parties for the use of LAMP, and if such third parties were able to independently develop or license the ability to detect amplified genetic material, then our business could be harmed. A termination of this license would result in the loss of significant rights and would restrict our ability to commercialize our COVID-19 test kit.

The Eiken Agreement will terminate on the expiration date of the last to expire valid claim of the Eiken Licensed Patents in any country. Eiken may terminate the Eiken Agreement upon (1) not receiving any royalties on licensed products for a certain period of time after sale of such products commences, (2) an uncured breach by us or our affiliates, (3) our bankruptcy or insolvency or certain other bankruptcy or insolvency events, (4) the assignment or attempt to assign the Eiken Agreement in violation of the Eiken Agreement or (5) a challenge by us or our affiliates of the validity of any of the Eiken Licensed Patents.

If we are determined to have breached the Eiken Agreement, Eiken would have the right to terminate the Eiken Agreement, which would result in the loss of our rights to the patents licensed to us, and we would therefore not be able to sell and/or market our test kits that are covered by those patents licensed to us. This would adversely affect our competitive business position and harm our business prospects. Moreover, disputes, arbitration, litigation or other proceedings with Eiken could last for an extended period of time, may not be resolved in a favorable manner and could result in substantial damages payable by us. In addition, the cost to us in defending or initiating any arbitration, litigation or other proceeding relating to the Eiken Agreement, even if resolved in our favor, could be substantial, and arbitration, litigation or other proceedings would divert our management's attention. Uncertainties resulting from the initiation and continuation of arbitration, litigation or other proceedings could adversely affect our business operations and delay our commercialization efforts and also result in reputational harm.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below under "Risks Related to Our Intellectual Property—We are dependent on patents and other intellectual property licensed from others and may become dependent on other patents or other intellectual property licensed from others in the future. If we lose our licenses for intellectual property that is important to our business, we may not be able to continue developing or selling our test kits." If we or Eiken fail to adequately protect this intellectual property, our ability to commercialize our test kits would suffer and our business would be harmed.

If we are not successful in leveraging our platform to discover, develop and commercialize additional test kits, our ability to expand our business and achieve our strategic objectives would be impaired.

While the global COVID-19 pandemic remains our current and primary focus, we believe our flexible platform enables us to launch different test kits for other infectious diseases. Capitalizing on the flexibility of our platform is a key pillar to our strategy, which we believe will enable us to focus on other test kits, including influenza. We plan to conduct additional research and development activities to explore the potential of our platform to be used in additional indications, including other infectious diseases such as STIs and respiratory syncytial virus, but we may not be successful in developing such additional indications in a timely manner or at all. Moreover, identifying new test kits requires substantial technical, financial and human resources, whether or not any test kits are ultimately developed or commercialized, which may divert management's attention away from our core business. We may pursue what we believe is a promising opportunity to leverage our platform only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that certain test kits or our platform in general has risks that were previously unknown or underappreciated. Our strategy of pursuing the value of our platform over a long time horizon and across a broad array of respiratory viruses may not be effective. In the event material decisions with respect to our strategy turn out to be incorrect or sub-optimal, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize

what we believe is the potential of our platform. The success of any new test kits or enhancements to our platform will depend on several factors, some of which are outside of our control, including our ability to:

- assemble sufficient resources to acquire or discover additional test kits or enhancements;
- properly identify and anticipate physician and patient needs;
- develop and introduce new test kits and enhancements in a timely manner;
- demonstrate, if required, the accuracy and usability of new test kits and enhancements with data from pre-clinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for expanded indications, new test kits or enhancements;
- be fully FDA-compliant with marketing of new devices or modified products;
- produce new test kits in commercial quantities at an acceptable cost; and
- provide adequate training to potential users of our test kits and provide adequate updated training to potential users of test kits that contain enhancements or alterations.

If we are unable to develop or improve test kits, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

In addition, we may choose to focus our efforts and resources on potential test kits or indications that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

If our test kits do not perform as expected, our operating results, reputation and business will suffer.

Our success depends on our ability to provide reliable test kits 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 in our clinical trials, particularly with respect to our COVID-19 test kit, may not continue or be indicative of actual future performance.

Our test kits use 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. If our test kits 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 will 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.

Operational, technical, user and other difficulties may adversely affect test performance, harm our reputation, impact the commercial attractiveness of our test kits and 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.

If we cannot provide quality technical and customer and user support, we could lose customers and our business and prospects will suffer.

The introduction of our test kits into our customers' existing workflows, and in the OTC context, our users' homes, and ongoing customer and user support can be complex. Accordingly, we need trained technical and customer and user support personnel. Hiring technical and customer and user support personnel is very competitive in our industry due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our platform at a technical level. To effectively support potential new customers and ultimately users, we will need to substantially develop a technical and customer and user support staff. 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 are unable to successfully expand our sales and marketing to match our growth, our business may be adversely affected.

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 our test kits, applicable federal and state laws and regulations and our internal policies and procedures, requires significant time, expense and attention. In addition, our EUA applications with respect to our COVID-19 test kit specifies 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.

We plan to dedicate significant financial and other resources to our marketing programs, which may require us to incur significant upfront costs. Our business and gross margins would be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue.

In addition, we believe that developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our test kits and attracting new customers. Brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our test kits.

We are highly dependent on our senior management team and key personnel and our business could be harmed if we are unable to attract and retain personnel necessary for our 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 and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals and scientists as well as contract employees could result in delays in product development and harm 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 in our market 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 will in the future issue, stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, 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 development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain "key man" insurance policies on the lives of these people or the lives of any of our other employees.

Many of the other medical device and diagnostic companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. They may also provide more diverse

opportunities and better chances for career advancement. Some of these characteristics are more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize our test kits will be limited.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

As of December 31, 2020, we had 57 full-time employees. As our sales and marketing strategies develop and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Since our inception, we have experienced growth and anticipate further growth in our business operations. This future growth could strain our organizational, administrative and operational infrastructure, including quality control, operational, finance, customer service and sales organization management. We expect to continue to increase our headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, customer service personnel, and sales and marketing staff and improve and maintain our platform to properly manage our growth. Rapid expansion in personnel could mean that less experienced people develop, market and sell our test kits, 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, our business may be harmed. We may not be able to maintain the quality or expected turnaround times of our test kits, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely, efficient and effective manner could adversely affect our operations. In addition, as a result of being a public company, we are obligated to develop and maintain effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may negatively impact investor confidence in our company and, as a result, the value of our common stock.

We may need to raise additional capital to fund our existing operations, develop our platform, commercialize new products or expand our operations.

Based on our current planned operations, we expect that our existing cash, including the net proceeds from our recent initial public offering, or IPO, will enable us to fund our operating expenses for at least 12 months from the date hereof. If our available cash and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including because of failure to secure additional regulatory approvals for our test kits, lower than anticipated or non-existent demand or reimbursement levels for our test kits, or otherwise, we may seek to issue equity or convertible debt securities, enter into a credit facility or another form of third-party funding, seek other debt financing or enter into collaborations or licensing arrangements.

We may 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 further scale up the manufacturing of our test kits, and if user

demand warrants such increase in scale, to increase our sales and marketing efforts to drive market adoption of our test kits and address competitive developments, and to finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, some of which are beyond our control, including:

- the cost and timing of additional regulatory clearances or approvals for our test kits and any future test kits;
- our ability to achieve and maintain revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements in the prescription at-home channel with commercial third-party payors and government payors;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our COVID-19 test kit;
- our rate of progress in, and cost of research and development activities associated with, our influenza test kit;
- the effect of competing technological and market developments, including developments in COVID-19 vaccination and therapeutics;
- the potential cost of and delays in test kit development as a result of any regulatory oversight applicable to our test kits;
- the scope, rate of progress and cost of our current and future clinical trials;
- the costs associated with any product recall that may occur;
- the costs of attaining, defending and enforcing our intellectual property rights; and
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish.

Additional funding may not be available on acceptable terms, or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or test kits or grant licenses on terms that may not be favorable to us.

In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic and actions taken to slow its spread, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development, manufacturing or commercialization of our COVID-19 test kit, our influenza test kit, or other research and development initiatives. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

The sizes of the markets for our test kits may be smaller than we estimate.

Our estimates of the annual addressable markets for our COVID-19 test kit and our influenza test kits are based on a number of internal and third-party estimates. For example, our estimates for the COVID-19 diagnostic testing market include, but are not limited to, estimates relating to the number of times per week healthcare workers would be tested, the time period for which tests may be required, administered or sought, as well as the assumed rate at which such test kit will be reimbursed, or the assumed prices

at which we can sell our COVID-19 test kit for. In addition, our estimates for the influenza diagnostic testing market are based on the population of people who experienced ILI symptoms during the previous flu season, as estimated by the number of people who purchased OTC cold and flu medication. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. If the actual number of customers who would benefit from our test kits, the price at which we can sell test kits or the annual addressable market for our test kits is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated, and thus are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability, or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular test kit or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our test kits and any future test kits may be harmed, which could harm our business, operating results, prospects or financial condition.

In addition, even if our clinical trials are successfully completed, their results may not support our future product claims and the FDA may not agree with our conclusions regarding these results. The clinical trial process may fail to demonstrate that our test kits are safe and effective for the proposed indicated uses, which could cause us to abandon a test kit and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our test kits and generate revenue.

Deficiencies in the components of our test kits could result in field actions, recalls, substantial costs and write-downs and could harm our reputation, business and financial results.

Our test kits are subject to various regulatory guidelines and involve complex technologies. The FDA and similar foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture that could affect patient safety. Manufacturers may, under their own initiative, conduct a product notification or recall to inform physicians of changes to instructions for use or if a deficiency in a device is found or suspected.

Identified quality problems, such as failure of critical components, including batteries and light-emitting diode, or LED, lights, or the failure of third parties to supply us with sufficient conforming quantities of these components, could impact the availability of our test kits in the marketplace or lead to adverse clinical events that could cause us to amend, repeat or terminate clinical trials. In addition, test kit improvements, redundancies or failure to sell a test kit before its expiration date could result in scrapping or expensive rework of test kits, and our business, financial condition or results of operations could suffer. Test kit complaints, quality issues and necessary corrective and preventative actions could result in communications to customers or patients, field actions, the scrapping, rework, recall or replacement of test kits, substantial costs and write-offs, and harm to our business reputation and financial results. Further, these activities could adversely affect our reputation with those in the medical community, as well as our distributor customers and end-users, which could materially adversely affect our earnings, results and financial viability.

As a result, any identified quality issue can both harm our business reputation and result in substantial costs and write-offs, which in either case could materially harm our business and financial results.

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

The marketing, sale and use of our test kits, if approved, could lead to the filing of product liability claims where someone may allege that our test kits 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 our test kits. See the risk factor "—The misuse or off-label use of our test kits may harm our reputation or the image of our test kits 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 commercialize our test kits or new products;
- decreased demand for our 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 our test kits may delay the supply of those test kits to our customers and users 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 test kits, either of which could negatively affect our business, financial condition and results of operations.

Litigation and other legal proceedings may harm our business.

We have been, and may become, involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions and other legal proceedings or investigations, which 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. Litigation is 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 our test kits, even if the regulatory or legal action is unfounded or not material to our operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations (including our clinical trials) could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, including the COVID-19 pandemic, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our ability to obtain components for our test kits could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Emeryville, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We rely substantially on Jabil to manufacture our COVID-19 test kit initially at manufacturing facilities located in Michigan and began manufacturing activities in the Dominican Republic in the second quarter of 2021. Over time and as automation efforts improve, we and Jabil may relocate manufacturing to one more additional facilities, which may include additional facilities located outside of the United States. Should Jabil's current or future manufacturing facilities be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, or should events such as political unrest unfold, it could take months to relocate or rebuild, during which time our manufacturing would cease or be delayed and our COVID-19 test kit may be unavailable. Moreover, 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 resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. 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, physicians and other users to discontinue using our COVID-19 test kits, or harm our reputation, and we may be unable to reestablish relationships with such customers and users in the future. Consequently, a catastrophic event or business interruption at Jabil's current or future manufacturing facilities could harm our business, financial condition and results of operations.

If we or our third-party collaborators, including Jabil, experience significant disruptions in performing their services for us, our business may be harmed.

We and our third-party collaborators, including Jabil, depend on information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our test kits, as well as for accounting, data storage, compliance, purchasing and inventory management. Our and our third-party collaborator's information technology systems 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 and our third-party collaborators 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 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 may 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.

Technological interruptions could disrupt operations, including the ability to timely ship and track product orders, project inventory requirements, manage supply chain and otherwise adequately service our customers or disrupt our customers' ability use our test kits. In addition, we will rely heavily on providers of transport services for reliable and secure point-to-point transport of test kits to our customers and users and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our test kits and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for test kits on a timely basis.

In the event we or our third-party collaborators experience significant disruptions, we may be unable to repair such systems 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. Currently, we carry business interruption coverage to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy

limits. 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.

In addition, the COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive information, we could incur liability and suffer reputational harm.

We may acquire other businesses or form other joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may pursue acquisitions of businesses and assets in the future. We also may pursue strategic alliances and additional joint ventures that leverage our platform and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. In addition, any pursuit of an acquisition and any potential integration of an acquired company also may disrupt ongoing operations and divert management attention and resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

We have a history of significant net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future.

We have incurred net losses since our inception. As of June 30, 2021, we had an accumulated deficit of $93.2 million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we grow our sales force and expand our marketing efforts to commercial our test kits, create relationships with customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

Our ability to use our net operating losses, or NOLs, to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had federal and state NOL carryforwards of approximately $53.3 million and $25.5 million, respectively. The federal NOLs include $11.0 million that may be used to offset up to 100% of future taxable income and the federal and state NOLs will begin to expire in the calendar year 2034, unless previously utilized. The NOL carryforwards subject to expiration could expire unused and be unavailable to offset future income tax liabilities.

Under the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may be carried forward indefinitely, but the deductibility of such federal NOLs in taxable years beginning after December 31, 2020 is limited. There is variation in how states will respond to the Tax Act and CARES Act. 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 in 2020 and before 2023.

Separately, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We determined that an ownership change occurred on October 9, 2015, but that all federal NOL carryforwards can be utilized prior to the expiration. As of August 7, 2020, we

experienced an ownership change, which resulted in limitations in our ability to utilize federal research and development credits of $1.6 million and state NOLs of $24.5 million.

In addition, we may in the future experience ownership changes, either as a result of our recent initial public offering or other changes in our stock ownership (some of which are not in our control). For these reasons, our ability to utilize our NOL carryforwards and other tax attributes to reduce future tax liabilities may be limited.

Risks Related to Government Regulation and Our Industry

We received two EUAs for our COVID-19 test kit and we submitted an amendment to our POC EUA. The FDA may not timely grant any additional or amended EUAs, if at all. For our existing EUAs and any new or amended 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 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. 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 kit. 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 November 17, 2020, we received an EUA from the FDA for our COVID-19 test kit for (1) prescription at-home use with self-collected nasal swab specimens in individuals aged 14 and older who are suspected of COVID-19 by their healthcare provider and (2) use at the POC with self-collected nasal swab specimens in individuals aged 14 and older, and in individuals aged 13 and under when the specimen is collected by a healthcare provider at the POC. All prescribing healthcare providers will be required to report test results to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics, or LIVD, Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. On April 9, 2021, we received an EUA from the FDA for our COVID-19 test kit for OTC non-prescription use among symptomatic and asymptomatic individuals aged 14 and older (with self-collection) and children aged two to 13 (with parent collection).

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. Such revocation could materially adversely impact our business in a variety of ways, including if our COVID-19 test kit is not yet approved by the FDA under a traditional approval pathway and if we and Jabil have invested in the supply chain to provide our COVID-19 test kit under an EUA, and would require us to obtain a 510(k) or other marketing authorization from the FDA. If the FDA revokes our existing EUAs prior to us having received regulatory approval to commercialize our COVID-19 test kit through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business.

Our business and sale of our test kits are subject to extensive regulatory requirements, including compliance with labelling, manufacturing and reporting controls. If our existing EUAs for our COVID-19 test kit are revoked or withdrawn, we will need to utilize other pathways to obtain marketing authorization. Our influenza test kit also will require marketing authorization from the FDA. If we fail or are unable to timely obtain the necessary EUA, 510(k) clearances, de-novo authorizations, or premarket approval, or PMA, approvals for new products or for the use of our test kits for additional indications, our ability to generate revenue could be materially harmed.

Our test kits are classified as medical devices and are subject to extensive regulation in the United States by the FDA and other federal, state and local authorities and by similar regulatory authorities in overseas jurisdictions. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, including directions for use, processes, controls, quality assurance, packaging, storage, distribution, installation and servicing;
- pre-clinical studies and clinical trials;

- establishment registration and listing;
- test kit safety and effectiveness;
- marketing, sales and distribution;
- recordkeeping procedures;
- advertising and promotion;
- premarket authorization (510(k), PMA, de-novo, EUA);
- corrections and removals and recalls;
- post-market surveillance, including reporting of deaths or serious injuries, and malfunctions that, if they were to recur, would be likely to cause or contribute to a death or serious injury; and
- product import and export.

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).

In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device. Substantial equivalence means that with respect to the proposed device being compared to the predicate device, the proposed device has the same intended use as the predicate device and the proposed device has the same technological characteristics as the predicate device, or has different technological characteristics but that the proposed device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness. Clinical data are sometimes required to support substantial equivalence.

In the PMA approval process, the FDA requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, pre-clinical study, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices and also novel devices that remain in Class III. Products that are approved from a PMA application generally need FDA approval of a PMA supplement before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k) clearance.

Another pathway, known as de-novo down-classification also can be used for lower risk devices for which there is no existing product code or predicate device. The Food and Drug Administration Modernization Act of 1997 established the de-novo down-classification procedure as a new route to market for low to moderate risk medical devices that automatically require a PMA due to the absence of a predicate device. This procedure allows a manufacturer whose novel device automatically requires a PMA to request down-classification of its medical device (to allow clearance through the 510(k) pathway) on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Manufacturers can request de-novo down-classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a "not substantially equivalent" determination. Under this pathway, the FDA is required to classify the device within 120 days following receipt of the de-novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

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.

Each of these processes can be expensive and lengthy, and with respect to a PMA, can entail significant user fees, unless exempt. The FDA's 510(k) clearance process usually takes from three to six months, but may take significantly longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or

longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining 510(k) clearances or PMA approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the United States, outside of the context of the EUA application process, our test kits 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 test kits 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 test kits under development or impact our ability to modify our currently approved or cleared test kits on a timely basis.

Modifications to our test kits may require new regulatory clearances or approvals or may require us to recall or cease marketing our test kits until clearances or approvals are obtained.

Once our test kits are initially cleared or approved, modifications to our test kits may require new regulatory 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 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 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 test kits in the future. For example, we may explore the development of a software component to our test kits, which may require new clearances or approvals from the FDA. If the FDA requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our test kits, as approved and as modified, which could require us to redesign our test kits 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 test kits 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 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 test kits in a timely manner, which in turn would harm our future growth.

If we or our contract manufacturers fail to comply with the FDA's Quality System Regulations, or QSR, our manufacturing operations could be interrupted and our test kit sales and operating results could suffer.

Although full compliance may not be required under an EUA, we will be required to comply with 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 test kits. The FDA enforces the QSR through periodic announced and unannounced inspections of 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 test kits;
- 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 test kits; or
- criminal prosecution.

Any of these actions could impair our ability to produce our test kits 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 our test kits on a timely basis and in the required quantities, if at all.

Our test kits are 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 approvals to commercialize our test kits.

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, Health Canada and numerous other governmental authorities in the United States as well as foreign countries where we may sell our test kits. Even after we have obtained EUA authorization, 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 test kits, if approved;
- warning letters or untitled letters;
- operating restrictions, including a partial or total shutdown of production on our test kits for any indication;

- refusal to issue export approvals or certifications;
- obtaining injunctions preventing us from shortage or distributing our products;
- commencing criminal prosecutions; and
- total prohibitions on our sales.

The incurrence or commencement of any such action would harm our reputation and cause sales of our test kits 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 the U.S. Department of Health and Human Services, or 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 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 POC 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.

Since we will offer prescription at-home, we expect to assist the prescribing providers in reporting test results. In a prescription at-home setting, the patients will be expected to report their respective results back to the prescribing health care providers who will be responsible for reporting the results to the appropriate public health authorities. We expect to provide two methods to facilitate such reporting, including through an on-package photo guide that would allow users to upload results to secure physician portals and through web-based test results registration reporting. We believe these processes would fulfill our reporting obligations. Additionally, we believe that these methods are secure and in compliance with applicable health information privacy laws, such as HIPAA. If governmental authorities conclude that our reporting processes do not comply with applicable law, we or the prescribing physician may be subject to penalties and other damages.

If our test kits cause or contribute to patient injuries or otherwise malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device may have caused or contributed to a patient death or serious injury or has or may have malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our test kits also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. 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.

Our test kits or any component thereof may be subject to product recalls in the future. A recall of our test kits, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our test kits, 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, under their own initiative, recall a product 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 one of our distributors could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our test kits would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. 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 test kits. A recall announcement by us could harm our reputation with customers and negatively affect our business, financial condition, and results of operations. In addition, the FDA or other agency could take enforcement action for failing to report the recalls when they were conducted.

If we initiate a recall, including a correction or removal, for one of our test kits, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our test kits, 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 misuse or off-label use of our test kits may harm our reputation or the image of our test kits 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 test kits 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 EUAs, 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 EUAs, our COVID-19 test kit must comply with certain labeling requirements, including the label that our COVID-19 test kit has not been FDA cleared or approved but has been authorized by the FDA under an EUA and that our COVID-19 test kit 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 test kits in the marketplace could be impaired.

Furthermore, the use of our test kits 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 patients 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 kit 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 test kits 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 kit we advance into clinical trials may not have favorable results in later clinical 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 kit, 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 test kits 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.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our test kits.

We do not have the ability to independently conduct our pre-clinical studies and clinical trials for our test kits and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical 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 test kits on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

Our collection, use, storage, disclosure, transfer and other processing of personal information, could give rise to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations and prospects.

In the course of our operations, we collect, use, store, disclose, transfer and otherwise process an increasing volume of personal information, including from our employees and third parties with whom we conduct business. The collection, use, storage, disclosure, transfer and other processing of personal information is increasingly subject to a wide array of federal, state and foreign laws and regulations regarding data privacy and security, including comprehensive laws of broad application, such as the European Union General Data Protection Regulation, that are intended to protect the privacy of personal information that is collected, used, stored, disclosed, transferred and otherwise processed in or from the governing jurisdiction. As we seek to expand our business, we are, and may increasingly become, subject to various laws, regulations and standards, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as FDA human subject protection regulations.

In many cases, these laws and regulations apply not only to third-party transactions, but also to transfers of information between or among us, any affiliates and other parties with whom we conduct business. These laws, regulations and standards 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 may harm our business, financial condition and results of operations. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

We are subject to diverse laws and regulations relating to data privacy and security. In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacy rights. For example, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. 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. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA has been amended several times, 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. State laws are changing rapidly and there is 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 and services involving data are offered, all of which may harm our business, financial condition and results of operations.

In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. 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 laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our test kits. If so, 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, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. 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 users and harm our business, financial condition and results of operations.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements 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 concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Complying with these numerous, complex and often changing regulations is expensive and difficult. Any failure or perceived failure by us or our service providers to comply with our posted privacy policies or with any applicable federal, state or similar foreign laws, regulations, standards, certifications or orders relating to data privacy, security or consumer protection, or any compromise of security that results in the theft, unauthorized access, acquisition, use, disclosure, or misappropriation of personal information or other user data, could result in significant fines or penalties, negative publicity or proceedings or litigation by governmental agencies or consumers, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, penalties or judgments, one or all of which could require us to change our business practices or increase our costs and could materially and adversely affect our business, financial condition and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and 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 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 FCA, which prohibits, 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 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 California Consumer Protection Act, or CCPA, which became effective January 1, 2020, and gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as 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, as defined by such law, 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, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists 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 test kits, 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.

In connection with our recent initial public offering, 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 reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets.*

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our test kits or the coverage and reimbursement available for our test kits and could limit the acceptance and availability of our test kits. The adoption of proposals to control costs could harm our business, financial condition and results of operations.

Since the start of the COVID-19 pandemic, Congress has passed several bills addressing coverage and payment for COVID-19 diagnostic tests and related services, including mandates for coverage and payment of certain tests. Further federal legislative action to address the ongoing pandemic is expected. Future legislation may change current laws to adversely affect coverage and reimbursement of our test kits, which could harm our business.

For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act or the ACA, was a sweeping measure that expanded healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and people, the provision of subsidies to eligible people enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the current U.S. presidential administration to repeal or replace certain aspects of the ACA. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain people who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the Further Consolidated Appropriations Act of 2020 permanently eliminates, effective January 1, 2020, the ACA-mandated medical device tax and the "Cadillac" tax on high-cost employer-sponsored health coverage and, effective January 1, 2021, also

eliminates the annual fee imposed on certain health insurance providers based on market share. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will affect the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2021. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The ACA, as currently enacted or as amended in the future, may harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our test kits, once approved;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Various new healthcare reform proposals are emerging at the federal and state level, and additional legislative measures to address the COVID-19 pandemic are expected. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business, and could expose us to liability if our use of such hazardous materials causes injury.

Our manufacturing processes currently require the controlled use of potentially harmful chemicals. We cannot eliminate the risk of accidental contamination or injury to contracted employees from offshore or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could negatively impact our reputation, financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

In addition, because our test kit contains electronic components and batteries which are purchased from third-party vendors, we may be required under rules promulgated by the SEC governing disclosure of the use of "conflict minerals" (tin, tungsten, tantalum and gold) to determine whether those minerals are necessary to the functionality or production of our test kits and, if so, conduct a country of origin inquiry with respect to all such minerals. If any such minerals may have originated in the Democratic Republic of the Congo, or DRC, or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those conflict minerals to determine if they originated in one of the covered countries and, if so, whether they

financed or benefited armed groups in the covered countries. Disclosures relating to the products that may contain conflict minerals, the country of origin of those minerals and whether they are "DRC conflict free" must be provided in a Form SD (and accompanying conflict minerals report, if required, to disclose the diligence undertaken by us in sourcing the minerals and our conclusions relating to such diligence). If we are required to submit a conflict minerals report, that report must be audited by an independent auditor pursuant to existing government auditing standards. Compliance with this disclosure rule may be very time-consuming for our management and personnel (as well as time-consuming for our suppliers) and could involve the expenditure of significant amounts of money by us and them. Disclosures mandated by this rule, which can be perceived by the market to be "negative," may cause customers to refuse to purchase our test kits. The cost of compliance with the rule could adversely affect our results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent or other intellectual property protection for any test kits we develop or for our platform, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize test kits and platform similar or identical to ours, and our ability to successfully commercialize any test kits we may develop, and our platform, may be harmed.

As with other medical device companies, our success depends in large part on our ability to obtain, maintain and solidify a proprietary position for our current and any future test kits, which will depend upon our success in obtaining effective patent protection in the United States and other countries that cover, and other intellectual property with respect to, such test kits, their manufacturing processes and their intended methods of use and enforcing those patent claims once granted as well as our other intellectual property. In some cases, we may not be able to obtain issued patent claims or other intellectual property covering our technologies which are sufficient to prevent third parties, such as our competitors, from utilizing our platform. Any failure to obtain or maintain patent and other intellectual property protection with respect to our current and any future test kits 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, including Eiken, 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 our licensors or licensees fail to adequately protect this intellectual property or if we do not have exclusivity for the marketing of our test kits, 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. For example, we rely on Eiken to maintain the patents and otherwise protect the intellectual property we license from Eiken pursuant to the Eiken License and Eiken may not successfully prosecute, maintain and protect such patents and intellectual property or may determine not to pursue litigation against third-parties that are infringing these rights, or may pursue litigation less aggressively than we would.

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 test kits. 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 our current and any future test kits, which may harm our business. Furthermore, even if they are unchallenged, our patents may not adequately protect our current and any future test kits, provide exclusivity for such test kits 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 test kits 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 test kits is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our current and any future test kits.

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 our current and any future test kits and services, 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 our current and any future test kits and services under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future test kits, patents protecting our current and any future test kits might expire before or shortly after such test kits are commercialized. For information regarding the expiration dates of patents in our patent portfolio, see Part I, Item 1 “Business—Intellectual Property” in our 2020 Annual Report on Form 10-K. 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 test kits 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 test kits 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 test kits 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 test kits 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.

Additionally, 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 test kits. 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 test kits, which could harm our business, financial condition and results of operations.

We are dependent on patents and other intellectual property licensed from others and may become dependent on other patents or other intellectual property licensed from others in the future. If we lose our licenses for intellectual property that is important to our business, we may not be able to continue developing or selling our test kits.

We have obtained licenses that give us rights to third-party intellectual property that is necessary or useful to our business. The license agreements covering our test kits impose various obligations on us. One or more of our licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license. If we materially breach the obligations in our license agreements, the licensor typically has the right to terminate the license and we may not be able to market products that were covered by the license, which could adversely affect our competitive business position and harm our business prospects. In addition, any claims brought against us by our licensors could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations.

Patents covering our current, and any future test kits, or our technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations.

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, allow third parties to commercialize our platform or our current and any future test kits and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize test kits 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 test kits, or limit the duration of the patent protection of our current and any future test kits 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 our current and any future test kits, 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 our current and any future test kits 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 our current and any future test kits 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 generic or determined to be violating or infringing on other marks. We may not be able to protect 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 and 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 medical device industry is characterized by intellectual property litigation and in the future 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 our existing or future test kits.

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 test kits, 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 formal freedom to operate analysis for patents related to our test kits, we may not be aware of issued patents that a third-party might assert are infringed by our current or any future test kits, which could materially impair our ability to commercialize our current or any future test kits. Even if we diligently search third-party patents for potential infringement by our current or any future test kits, we may not successfully find patents that our current or any future test kits may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our current or future test kits. 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 test kits and technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. Additional 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 our current and any future test kits 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 test kits. 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 test kits in commercially important territories, or force us to cease some of our business operations, which could harm our business. Many of our employees were previously employed at, and many of our current advisors and consultants are 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 test kits or technology, which could harm our business, financial condition and results of operations.

We have limited 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 our current and any future test kits 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 test kits 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 test kits and, further, may export otherwise infringing test kits to territories where we have patent protection but enforcement is not as strong as that in the United States. These test kits may compete with our current and any future test kits, 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 test kits 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 our current and any future test kits.

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 our current and any future test kits.

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 test kits.

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 test kits. 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 test kits. 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 test kits. 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 test kits. 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 our current and any future test kits.

The medical device 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 any test kits 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.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our current and any future test kits infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our current and any future test kits, parts of our current and any future test kits, 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 our current or future test kits 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 our current and any future test kits, which could harm our ability to commercialize any test kit 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 applicable test kits 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 our current and any future test kits, 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 infringing test kits 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 our infringing test kits 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 medical device industry, our employees, consultants and advisors may be currently or previously employed or engaged at universities or other medical device or healthcare 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 test kits that are similar to our current and any future test kits or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our current and any future test kits 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 kits 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 test kits 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 kits 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 test kits 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 test kits 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 our current and any future test kits, 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.

If our third-party manufacturing partner, Jabil, does not respect our intellectual property and trade secrets and produce competitive test kits using our designs or intellectual property, our business, financial condition and results of operations would be harmed.

We conduct most of our manufacturing activities through Jabil at its Michigan facilities and began manufacturing activities in the Dominican Republic in the second quarter of 2021. Although the Jabil MSA generally precludes Jabil from misusing our intellectual property and trade secrets, or using our designs to manufacture test kits for our competitors, we may be unsuccessful in monitoring and enforcing our intellectual property rights and may find counterfeit goods in the market being sold as our current and any future test kits or test kits similar to ours produced for our competitors using our intellectual property. Although we take steps to stop counterfeits, we may not be successful and network operators who purchase these counterfeit goods may experience product defects or failures, harming our reputation and brand and causing us to lose future sales. Any of the foregoing could harm our business, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

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 limited trading volume. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, these factors including:

- the receipt of additional or amended EUAs from the FDA for our COVID-19 test kit and the timing thereof;
- our ability to obtain and maintain regulatory approvals for our test kits;
- changes in laws or regulations applicable to our test kits;
- adverse developments concerning Jabil or any of our third-party collaborators and suppliers, including our sole-source suppliers;
- our inability to obtain adequate product supply for any approved test kit or inability to do so at acceptable prices;
- the degree and rate of physician and market adoption of any of our test kits, and initially our COVID-19 test kit;
- announcements by us or our competitors of significant business developments, diagnostic technologies, acquisitions, or new offerings;
- negative publicity associated with issues related to our test kits;
- changes in the anticipated future size and growth rate of the COVID-19 and influenza diagnostic testing markets as a result of widely administered use of an efficacious vaccine or other treatment;
- the development of new vaccines and treatments for COVID-19 or the announcement of impending approval of such new vaccines or treatments;
- our inability to establish collaborations, if needed;

- future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of our common stock;
- performance or news releases by other companies in our industry including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls;
- general economic, regulatory and market conditions, including economic recessions or slowdowns;
- actual or anticipated fluctuations in our financial condition and results of operations, including as a result of anticipated or unanticipated demand based on seasonal factors;
- variance in our financial performance from expectations of securities analysts or investors;
- changes in our projected operating and financial results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

Broad market and industry fluctuations, as well as general economic, pandemic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small public float of shares of our common stock on the Nasdaq Global Select Market, or Nasdaq, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against companies that have experienced volatility or following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Substantial future sales and issuances of our common stock could cause the market price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock.

In addition, certain of our stockholders have registration rights that would require us to register shares owned by them for public sale in the United States. We have also filed a registration statement to register shares reserved for future issuance under our equity compensation plans. As a result, subject to the satisfaction of applicable exercise periods and applicable volume and restrictions that apply to affiliates, the shares issued upon exercise of outstanding stock options or upon settlement of outstanding restricted stock unit awards are available for immediate resale in the United States in the open market.

Sales of our shares could also impair our ability to raise capital through the sale of additional equity securities in the future and at a price we deem appropriate. These sales could also have an adverse effect on the trading price of 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.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock beneficially own a significant percentage of our outstanding 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.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then-current debt instruments. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We are an emerging growth company and a smaller reporting company and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

We are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Investors may find our common stock less attractive as a result of our reliance on these exemptions. 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.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf, (2) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, (5) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, and (6) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

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 and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find either exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We expect such expenses 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 Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the

senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel will have to 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. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we may not achieve profitability in the future and that, if we do become profitable, we may not sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our test kits to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

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

We will be required, pursuant to Section 404 of the Sarbanes–Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2021, which is the year covered by the second annual report following the completion of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time.

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 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 or significant deficiency 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.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results 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 our financial statements in conformity with generally accepted accounting principles 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 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 revenue accounting standard, Accounting Standards Codification, or ASC, Topic 606, management makes judgments and assumptions based on our interpretation of the new standard. The 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 standard. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, 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.

Changes in tax law and regulations may have a material adverse effect on our business, financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by the Internal Revenue Service, the U.S. Treasury Department and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, financial condition, results of operations, and cash flow. We urge investors to consult with their legal and tax advisers regarding the implication of potential changes in tax laws on an investment in our common stock.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

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, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act, 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 or may in the future conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties outside of the United States to sell our test kits internationally once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other third-party 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 are subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA, in which violations of these laws could result in substantial penalties and prosecution.

For any operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, our internal control policies and procedures and employee training and compliance programs designed to deter prohibited practices ultimately may not be effective in preventing our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could harm our business, financial condition and results of operations.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts publish unfavorable or inaccurate research about our business, our common stock price and trading volume could decline.

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We expect that only a limited number of analysts will cover our company following our initial public offering. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None of the following transactions involved any underwriters, underwriting discounts or commissions, or any public offering unless specified otherwise. Unless otherwise specified below, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. 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 on the share 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.

Stock Option and Restricted Stock Unit Grants

From January 1, 2021 through February 8, 2021, we granted certain of our directors, executive officers, employees and consultants options to purchase an aggregate of 601,613 shares of common stock with a weighted-average exercise price of $17.00 per share. During this period, options to purchase an aggregate of 22,535 shares of common stock were exercised for aggregate consideration of approximately $0.02 million.

Use of Proceeds From Registered Securities

On February 9, 2021, we sold 10,350,000 shares of our common stock in connection with our IPO, including 1,350,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at public offering price of $17.00 per share for an aggregate offering price of approximately $175.9 million. The offer and sale of all the shares in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-252164) that was declared effective by the SEC on February 4, 2021. BofA Securities, Inc. and William Blair & Company, L.L.C. acted as lead bookrunning managers and LifeSci Capital LLC acted as co-manager.

The underwriting discounts and commissions for our IPO totaled $12.3 million. We incurred additional costs of approximately $3.7 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $16.0 million. Thus, net offering proceeds to us, after deducting underwriting discounts, commissions and offering expenses, were $159.9 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. There has been no material change in the use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on February 8, 2021.

Repurchases of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit No.	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Lucira Health, Inc.	8-K	001-39976	3.1	February 9, 2021
3.2	Amended and Restated Bylaws of Lucira Health, Inc.	8-K	001-39976	3.2	February 9, 2021
10.1*	Employment Agreement, dated as of May 10, 2021, by and between the registrant and Kevin Collins.				
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 Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2*#	Certification of Principal 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 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 (embedded within the Inline XBRL document)				

* Filed herewith.

\+ Indicates management contract or compensatory plan.

\# The certifications furnished in Exhibits 32.1 and 32.2 hereto are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Lucira Health, Inc. 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-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements 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.

LUCIRA HEALTH, INC.

Date: August 13, 2021

By: /s/ Erik T. Engelson
Erik T. Engelson
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 13, 2021

By: /s/ Daniel George
Daniel George
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 10.1

LUCIRA HEALTH, INC.

Kevin Collins **May 6, 2021**

Dear **Kevin**,

On behalf of Lucira Health Inc. (the "***Company***"), it is my pleasure to offer you employment beginning on **May 27, 2021** (the "**Start Date**"). This letter shall serve to confirm the terms of your employment with the Company.

If the terms below are acceptable to you, please sign this confirmation letter where indicated andreturn it to me.

SUMMARY:

Position. Your initial position will be **Chief Revenue Officer**. The responsibilities associated with this position are outlined below in Exhibit A and may change due to the dynamicnature of the job. You will primarily work at our office located in Emeryville, CA. Of course, theCompany may change your position, duties, and work location from time to time in its discretion.

Salary. Your initial base salary will be $440,000.00 per year, less payroll deductions and withholdings, paid on the Company's normal payroll schedule. All reasonable business expenses that are documented by you will be reimbursed that are incurred in the ordinary course of business.

Annual Discretionary Bonus. You will also be eligible to earn an annual discretionary bonus of up to 40% of your base salary. The amount of this bonus will be determined in the sole discretion of the Company and based, in part, on your performance and the performance of the Company during the calendar year, as well as any other criteria the Company deems relevant, as set forth in the Company's Employee Bonus Program or any successor bonus program sponsoredby the Company. The Company will pay you this bonus, if any, no later than March 15th of the following calendar year. The bonus is not earned until paid and no pro-rated amount will be paidif your employment terminates for any reason prior to the payment date.

Sales Commission Plan. While you remain employed by the Company, you will also be eligible to earn sales commissions with a target of 30% of your base salary. The terms and conditions for earning sales commissions will be governed by the Company's Sales Commission Plan, which will be acceptable to you and the Company. You will be provided with a copy of theSales Commission Plan applicable to you.

Equity Incentive Plan. Subject to approval by the Company's Board of Directors (the "***Board***"), the Company anticipates granting you Restricted Stock Units ("RSUs") that will approximate $2,150,000. The RSUs will be governed by the terms and conditions of the Company's 2021 Equity Incentive Plan (the "***Plan***") and will include a four year vesting schedule, under which 25% will vest 12 months after the vesting commencement date, and 3/48ths of the total shares will vest on the first day of the last month of each quarter thereafter, until either the RSUs are fully vested or your continuous service (as defined in the Plan) terminates, whichever occurs first with a one year cliff.

Benefits. During your employment, you will be eligible to enroll in the Company's standard employee benefit plans, including health, dental, and vision plans, and other benefit programs as they are adopted by the Company, subject to plan terms and generally applicable Company policies. Currently, the Company provides the following insurance coverages: $450 per month for health insurance ($200 for dependents) and 80% of the monthly cost for vision and dental insurance (50% for dependents). We will provide you more information regarding these plans upon your request. The Company may change compensation and benefits from time to time in its discretion.

Exempt Salaried Employee. We believe in working efficiently and we strive to uphold normal business hours from 9:00 a.m. to 6:00 p.m., Monday through Friday. However, as an exempt salaried employee, you will be expected to work the Company's normal business hours as well as additional hours as required by the nature of your work assignments, and you will not be eligible for overtime compensation.

At-Will Employment. It is our desire that our association be long-lasting and mutually rewarding. You should however understand that your employment with the Company is for no specified period and will be "at-will". As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without advance notice. Your employment at-will status can only be modified in a written agreement signed by you and by an officer of the Company. We request that, in the event of your resignation, you give the Company at least two (2) weeks' notice.

Prior Agreements and Restrictions. By signing this letter, you represent that you have full authority to accept this position and perform the duties of the position without conflict with any other obligations and you specifically warrant that you are not a party to any agreement that in any way prohibits or imposes any restriction on your employment with the Company, and your acceptance of this offer will not breach any agreement to which you are a party. You further represent that you are not involved in any situation that might create, or appear to create, a conflict of interest with respect to your loyalty or duties to the Company. You will provide the Company with copies of any relevant employment-related agreements with any former employer, including any non-compete agreement that you may have with another company. We also wish to emphasize that we are hiring you because we believe that you have general skills and experience that will benefit the Company. We are not hiring you to acquire any proprietary or confidential information of your prior employers and ask that you not bring any such confidential information with you, including trade secrets. You agree that you will not bring onto Company premises, or upload onto any Company system, any unpublished documents, information or property belonging to any former employer or other person to whom you have an obligation of confidentiality. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company. You also agree to honor all obligations to former employers during your employment with the Company.

Outside Activities. You agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting, advisory roles or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company; provided, however, that the Company acknowledges and agrees that you are currently and will continue to be an advisory board member of Alvarez Larrea Equipos Medicos Alem CIA. LTDA. and SofMedica Group SRL.

Confidential Information and Company Policies. As a Company employee, you will be expected to abide by Company rules and policies. As a condition of employment, you must sign and comply with the attached Employee Confidential Information and Invention Assignment Agreement which prohibits unauthorized use or disclosure of the Company's proprietary information, among other obligations. Upon your acceptance of this offer, please return to me a signed copy of this agreement.

Arbitration. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules- employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.**

In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate theclaims of more than one person or entity and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration.

This section shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "***Excluded Claims***"). In the event you intend to bring multiple claims, includingone of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator.

The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

Background Check: Proof of Right to Work. This offer is contingent upon a satisfactory reference check and satisfactory proof of your right to work in the United States. If the Company informs you that you are required to complete a background check, this offer is contingent upon satisfactory clearance of such background check. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

Acceptance of Offer; Entire Agreement. This letter, along with the Employee Confidential Information and Invention Assignment Agreement, sets forth the complete and exclusive terms of your employment with the Company and supersedes any prior representations or agreements made to you by anyone, whether written or oral. Changes in your employment terms, other than those changes expressly reserved to the Company's discretion in this letter, require a written modification signed by an officer of the Company. If any provision of this offer letter agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This letter may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

If you wish to accept the employment offer at under the terms described above, please sign and date this letter, along with the enclosed Employee Confidential Information and Inventions Assignment Agreement. This offer, if not accepted, will expire on **May 11, 2021**.

SIGNATURE PAGE FOLLOWS

I am delighted that you will be joining the Lucira Health team and I personally look forward to working together with you to build our company and improve healthcare around the world. If you have any questions, please do not hesitate to contact me.

Best regards,

/s/ Erik T. Engelson
Erik T. Engelson
Chief Executive Officer
Lucira Health, Inc.

UNDERSTOOD AND ACCEPTED:

I accept this employment offer. The provisions stated in this letter supersede all prior discussions and offer negotiations.

Signed:	/s/ Kevin Collins
Date:	May 10, 2021
Start Date:	May 27, 2021

EXHIBIT A

RESPONSIBILITIES

The following summary is a partial list of the responsibilities associated with your job and is intended to illustrate initial job function. Due to the dynamic nature of the job, your duties and responsibilities may change over time.

SUMMARY:

As the Chief Revenue Officer, you are responsible for the company's revenue streams andleveraging knowledge of the roles both sales and marketing play in driving growth. You have ultimate accountability in aligning all revenue-generating departments and building strategic partnerships. Your cross-functional expertise will ensure sales and marketing communicate well, share information, and collaborate in content creation so that all messaging fits our targetcustomers.

PRIMARY RESPONSIBILITIES:

- Partner with other members of the executive team to execute the current corporate strategic plan, and develop future plans
- Ensure performance, strategy, and alignment of the organization's revenue-generating departments
- Manage a global sales team that can drive business growth across all customer segments and profiles, and share accountability with the marketing function forimproving the individual customer experience and strategy
- Help maximize reach and efficiency by adding new, scalable partners in a strategicway
- Build and foster creative teams committed to continuing our culture of innovation
- Monitor the revenue pipeline and leads, adjusting as necessary to create sustainablegrowth

YOU WILL REPORT TO: Erik T. Engelson, Chief Executive Officer.

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, Erik T. Engelson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lucira 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(s) 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)) 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) *Intentionally Omitted*

   (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(s) 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: August 13, 2021

By: /s/ Erik T. Engelson
Erik T. Engelson
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, Daniel George, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Lucira 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(s) 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)) 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) *Intentionally Omitted*

   (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(s) 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: August 13, 2021

By: /s/ Daniel George
Daniel George
Chief Financial Officer and Treasurer
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 Quarterly Report of Lucira Health, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 13, 2021

By: /s/ Erik T. Engelson
Erik T. Engelson
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Quarterly Report of Lucira Health, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 13, 2021

By: /s/ Daniel George
Daniel George
Chief Financial Officer and Treasurer
Principal Financial and Accounting Officer