UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K/A

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 4, 2021**

BOSTON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-54586**	**27-0801073**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

5900 Hollis Street, Emeryville, CA 95608
(Address of Principal Executive Offices)(Zip Code)

(510) 428-5300
(Registrant's telephone number, including area code)

354 Merrimack Street #4, Lawrence, MA 01843
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act: None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Explanatory Note

This Current Report on Form 8-K/A (this "Amendment") is being filed by Boston Therapeutics, Inc., a Delaware corporation (the "Company"), to amend its Current Report on Form 8-K (the "Original 8-K") filed with the Securities and Exchange Commission (the "SEC") on June 4, 2021, as amended on August 27, 2021, in connection with the consummation on June 4, 2021 of the transactions contemplated by that certain Agreement and Plan of Merger, dated January 26, 2021 (the "Merger Agreement"), by and among the Company, BTHE Acquisition Inc. ("Merger Sub") and Nanomix, Inc. ("Nanomix"), pursuant to which Merger Sub merged with and into Nanomix, with Nanomix surviving as a wholly-owned subsidiary of the Company (the "Merger"). On August 27, 2021, the Company filed an Amendment to the Original 8-K with the Commission to provide, among other things, (i) certain voluntary disclosures concerning the financial condition of the Company, as permitted by Item 8.01; (ii) the historical audited financial statements of Nanomix as of and for the years ended December 31, 2020 and 2019, and the unaudited condensed consolidated financial statements as of March 31, 2021 and for the three month periods ended March 31, 2021 and 2020, referred to in Item 9.01(a) below; and (iii) the unaudited pro forma condensed combined financial statements as of and for the three month period ended March 31, 2021 and for the year ended December 31, 2020, referred to in Item 9.01(b) below. The Company is filing this Amendment solely to provide certain voluntary disclosures concerning the Company's business and risk factors after consummation of the Merger, as permitted by Item 8.01. Except for the foregoing, this Amendment does not modify or update any other disclosure contained in the Prior 8-K.

Item 8.01 Other Events.

Nanomix's Management's Discussion and Analysis of Financial Condition and Results of Operations as of March 31, 2021 and for the three month periods ended March 31, 2020 and 2019, are filed herewith and attached hereto as Exhibits 99.1 and incorporated herein by reference. Nanomix's Management's Discussion and Analysis of Financial Condition and Results of Operations as of December 31, 2020 and for the year ended December 31, 2020 and 2019, are filed herewith and attached hereto as Exhibits 99.2 and incorporated herein by reference.

A discussion of the Company's business and risk factors associated with the business are filed herewith and attached hereto as Exhibits 99.6 and 99.7, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(a) ***Financial Statements of Business Acquired***

The audited financial statements of Nanomix as of and for the years ended December 31, 2020 and 2019, and the unaudited condensed consolidated financial statements as of March 31, 2021 and for the three month periods ended March 31, 2021 and 2020, are filed herewith as Exhibits 99.3 and 99.4, respectively, and are incorporated herein by reference.

(b) ***Pro Forma Financial Information***.

The unaudited pro forma condensed combined financial statements of the Company and Nanomix as of and for the three month period ended March 31, 2020 and for the year ended December 31, 2020, filed herewith and attached hereto as Exhibit 99.5, are incorporated herein by reference.

(d) ***Exhibits***

Below is a list of exhibits included with this Current Report on Form 8-K.

Exhibit No.	Document
99.1	Management's Discussion and Analysis of Financial Condition and Results of Operations of the Nanomix as of March 31, 2021 and for the three month periods ended March 31, 2021 and 2020 (filed as Exhibit 99.1 to the Company's Current Report on Form 8-K/A, as filed with the Securities and Exchange Commission on August 27, 2021, and incorporated herein by reference).
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations of the Nanomix as of December 31, 2021 and for the fiscal year ended December 31, 2020 and 2019 (filed as Exhibit 99.2 to the Company's Current Report on Form 8-K/A, as filed with the Securities and Exchange Commission on August 27, 2021, and incorporated herein by reference).
99.3	Audited financial statements of Nanomix as of and for the years ended December 31, 2020 and 2019 (filed as Exhibit 99.3 to the Company's Current Report on Form 8-K/A, as filed with the Securities and Exchange Commission on August 27, 2021, and incorporated herein by reference).
99.4	Unaudited condensed consolidated financial statements of Nanomix as of March 31, 2021 and for the three month periods ended March 31, 2021 and 2020 (filed as Exhibit 99.4 to the Company's Current Report on Form 8-K/A, as filed with the Securities and Exchange Commission on August 27, 2021, and incorporated herein by reference).
99.5	Unaudited pro forma condensed combined financial statements of the Company and Nanomix as of and for the three month period ended March 31, 2021 and for the year ended December 31, 2020 (filed as Exhibit 99.5 to the Company's Current Report on Form 8-K/A, as filed with the Securities and Exchange Commission on August 27, 2021, and incorporated herein by reference).
99.6	Business of the Company
99.7	Risk Factors of the Company
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

BOSTON THERAPEUTICS, INC.

By: */s/ David Ludvigson*
Name: David Ludvigson
Title: Chief Executive Officer

Date: November 5, 2021

BUSINESS

Overview

On June 6, 2021, we completed our merger, or the Merger, with Nanomix, Inc., a California corporation, or Nanomix. As consideration for the Merger, we issued to the shareholders of Nanomix 1,000,000 shares of a newly created Series C Convertible Preferred Stock of the Company (the "Preferred Stock"). Upon the effectiveness of the amendment to our Certificate of Incorporation to effectuate the reverse stock split of one-for-173, all such shares of Preferred Stock issued to Nanomix shareholders shall automatically convert into approximately 35,316,768 shares of common stock of the Company, the warrants to be assumed at closing may be exercisable into approximately 2,100,911 shares of common stock of the Company and the options and restricted stock units to be assumed at closing may be exercisable into approximately 6,070,842 shares of common stock of the Company. The shares of common stock issuable upon conversion of the Preferred Stock together with warrants, restricted stock units and options to be assumed on the closing date shall represent approximately 80% of the outstanding shares of Common Stock of the Company upon closing of the Merger.

After the Merger, our primary focus is transitioning to the development Nanomix's advanced mobile Point-of-Care (POC) diagnostic system that can be used in performing a wide range of in vitro diagnostic tests in many environments. Nanomix's goal is to provide laboratory quality testing for time sensitive medical conditions, at the first point of contact that a patient has with the healthcare system, no matter where that occurs. The Nanomix eLab® system is CE Marked, a 510(k) is currently in process, and Emergency Use Application (EUA) for COVID testing has been submitted to the FDA. Nanomix intends to market and sell this system for the detection and diagnosis of a variety of time sensitive medical conditions.

Prior to the Merger, we were a pre-clinical and clinical-stage pharmaceutical development company focused on the clinical development, outsourced contract manufacture and test marketing for commercialization of carbohydrate-based patented formulation of investigative materials as medical food, supplements, drug and drug combination, and other clinical exploratory out sourced exploratory peptide therapeutic options. Due to limited funding, our activity including any drug development during year ended December 31, 2020 was severely limited. Following the closing of the Merger, the Company intends to conduct a comprehensive review of strategic alternatives for our legacy products and product candidates pertaining to the commercialization of our therapeutic drugs including SUGARDOWN®, BTI-320 and IPOXYN. The Company does not expect to receive any form of material consideration in connection with such alternatives. In the event it is not able to dispose of these assets, the Company expects to cease all operations in connection therewith in order to avoid incurring any further associated expense.

Nanomix eLab System

Nanomix believes that quality healthcare should be available to consumers anywhere and anytime. The foundation of quality healthcare is timely information supporting a proper diagnosis and associated treatment. Our vision is to make healthcare accessible to patients without compromise, by delivering the highest quality, fastest, most cost-effective and portable detection systems that bring the patient and caregiver closer together.

The Nanomix eLab System is a proprietary diagnostic platform developed by Nanomix to meet the growing need for decentralized medical diagnostic solutions. The platform is designed to provide rapid test results in a handheld device at the first point of patient contact in locations that range from Emergency Departments, to long term and assisted care facilities, to urgent care and emergency medical response settings.

The Nanomix eLab system is a rapid, easy-to-use, quantitative detection platform that performs a range of in vitro diagnostic assays, such as electrochemical immunoassay and enzymatic assays. The platform consists of a hand-held analyzer and a disposable cartridge. The eLab System utilizes a proprietary nano-biosensor with multiple detection electrodes to generate multiple electrochemical assay results from a single patient sample. Specificity is generated by functionalizing each of the electrodes on the sensor for particular biomarkers. The sensor is incorporated into a single-use consumable microfluidics cartridge that processes the biological sample and reports its results through the handheld eLab System.

The eLab system is designed to be operated by medical and non-medically trained persons. An assay is run by inserting the cartridge into the eLab Analyzer. Following the prompts on the Analyzer interface, the user identifies the subject, scans a barcode on the consumable package, loads the test sample into the cartridge, and presses start. Assay results generally take between 10 and 15 minutes, from sample collection to answer. A wide variety of biomolecules with varying chemistries can be tested on a single device in one operation. The electrochemical detection system eliminates the need for ongoing instrument calibration and maintenance commonly associated with optical systems. Wireless connectivity provides for transmission of patient results to other devices for data sharing, management, and EMR integration.

Compared with other POC testing systems, the Nanomix eLab system provides testing in traditional laboratories as well as non-traditional decentralized environments with enhanced sensitivity and specificity, advanced multiplexing and multimodal capabilities, quantitative results, Bluetooth communication of results and an on board electronic data base of testing activities. The Nanomix eLab® system is CE Marked, a 510(k) is currently in process, and a COVID-19 test is being submitted to the FDA for Emergency Use Authorization.

Our strategy is to develop a menu of diagnostic tests for the detection and diagnosis of time sensitive medical conditions on the Nanomix eLab Analyzer and to sell, market and distribute the eLab Analyzer and associated tests on a worldwide basis.

Products

The Nanomix eLab is an in vitro diagnostic test platform for the quantitative determination of analytes in biological samples that include plasma, whole blood, and nasal swab specimens. The eLab system consists of a handheld analyzer, a sample transfer device and a disposable cartridge. The Nanomix eLab is a platform technology and Nanomix intends to develop a range of test cartridges compatible with Nanomix eLab analyzer. The key advantages of our approach are:

- Laboratory quality results;
- Multiplexing and multimodal testing;
- Quantitative determination of test results;
- Operates in distributed environments; and
- Electronic record storage with Bluetooth communication of results.

The eLab has been shown to be easily operated by non-medically trained personnel. The platform performs immunoassays and enzymatic assays. All tests run on the eLab Analyzer utilize the same disposable cartridge format.

Nanomix's first product, the S1 Panel Assay for use in aiding the diagnosis of critical infections, received CE marking for the assay and the eLab Analyzer in November of 2019. Filing of a 510(k) was started in 2020 through a third-party reviewer for the CRP assay. With the advent of the Coronavirus pandemic, Nanomix shifted to developing

COVID-19 testing products in April of 2020.

eLab Analyzer

The eLab Analyzer is a handheld portable instrument that operates via a touch screen using a simple instruction menu. The analyzer works from a rechargeable battery or wall power and can be operated during recharging. The eLab Analyzer contains electronics, a pneumatic system, a barcode scanner, data storage, USB connections, and Bluetooth communications. To use the eLab system, an operator signs in to the system and then follows the prompts on the eLab screen to run an assay, run controls, or review past test results. To run a test, the operator enters a patient ID and scans the consumable test package using the built-in bar code scanner. The barcode contains information about the test including manufacturing lot codes and expiration dating for the consumable. The operator loads the patient sample into the disposable cartridge and inserts the cartridge into the eLab analyzer. The operator is then prompted on the screen to activate the assay. The eLab automatically runs through to completion using the programmed test protocol specific for that assay. At conclusion of the test protocol, results are displayed on the screen and can be sent electronically via Bluetooth as selected by the operator. All test information is recorded in the onboard database. The instrument includes a robust control system and, if there are errors in processing, the eLab displays an error code on the screen.

COVID-19 Rapid IgG/IgM Test Panel

The Nanomix eLab COVID-19 Rapid IgG/IgM Panel is an electrochemical immunoassay test intended for qualitative detection of IgG and IgM antibodies (without differentiation) to SARS-CoV-2 in human venous whole blood and plasma (K2EDTA, lithium-heparin, sodium-heparin, sodium citrate).

Venous whole blood or plasma samples are collected and using a provided transfer device the sample is transferred to the single-use, microfluidic cartridge. The cartridge is then run on Nanomix eLab Analyzer, which will display results after about 10 minutes. The presence of SARS-CoV-2 antibodies is determined using a quantitative electrochemical reading which is then compared to a cutoff level to report a qualitative result of positive or negative.

An EUA for the COVID-19 Rapid IgG/IgM Test Panel was filed with the FDA in July 2020. In April of 2021, the FDA notified us that given the volume of EUA requests the Agency had received, FDA is having to prioritize EUA requests and they will not be reviewing our product as filed. Nanomix is currently tracking use cases and reviewing alternative approaches to market the COVID antibody test.

COVID-19 Antigen Test Panel

The Nanomix eLab COVID-19 Rapid Antigen Panel is an electrochemical immunoassay test intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in nasal (anterior nares) swabs from individuals who are suspected of COVID-19.

Nasal swab samples are collected using a provided swab and sample collection tube, then transferred to the single-use, microfluidic cartridge. The cartridge is then run on Nanomix eLab Analyzer, which will display results after about 15 minutes. The presence of SARS-CoV-2 antigen is determined using a quantitative electrochemical reading which is then compared to a cutoff level to report a qualitative result of positive or negative.

An EUA for the COVID-19 Antigen Test panel was submitted to the FDA in February of 2021. The Company received comments from the FDA in May and is currently conducting further clinical and analytical work requested by the FDA and intends to refile the EUA as soon as the additional work is complete.

S1 Assay Panel

The S1 Assay panel was developed as an aid in rapidly diagnosing critical infections including sepsis. The panel provides quantitative tests results for Lactate (LAC), C-Reactive Protein (CRP) and Procalcitonin (PCT) from a single plasma sample. The assay runs on the eLab Analyzer with results available in approximately 11 minutes, providing information rapidly versus the current diagnostic solutions which can take hours to provide a test result.

The Nanomix S1 Panel Cartridge quantitatively measures two biomarkers, CRP, and PCT and the metabolite Lactate (LAC) in lithium heparinized (Li-heparinized) plasma specimens.

CRP test results can be used to evaluate infection, tissue injury, and inflammatory disorders.

PCT test results can be used:

- To aid in decision making on antibiotic therapy for patient with suspected or confirmed lower respiratory tract infections (LRTI) defined as community acquired pneumonia (CAP) acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) in an inpatient setting or Emergency Department.
- To aid in antibiotic decision making from therapy to discontinuation of treatment for patients with suspected or confirmed sepsis.
- To aid in the risk assessment of critically ill patients on their first day of ICU admission for progression of severe sepsis and septic shock.
- To aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with sever sepsis or septic shock in the ICU or when obtained in the emergency department of other medical wards prior to ICU admission, using a change in PCT level over time.

LAC test results can be used in the diagnosis and treatment of lactic acidosis, monitoring tissue hypoxia, and diagnosis of hyperlactatemia and septicemia.

Each of the three tests provides important information about a patient's condition. Having all three of these answers in a short time period provides a healthcare provider with important information about the patient's status within the clinical window for infection diagnosis. All of the test results are used in the context of other information about the patient.

S1 Assay Panel use in Sepsis

One potential use of the S1 Assay panel is in the diagnosis of Sepsis. Sepsis has been highlighted as a global health crisis and there is intense pressure to improve management of sepsis from early identification to administration of antimicrobial therapy, monitoring and de-escalation of therapy.

Sepsis is the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure, and death. There are more than 49 million cases of Sepsis annually with more the 6 million associated deaths. Sepsis is the #1 cost of hospitalization in the U.S with costs for acute sepsis hospitalization and skilled nursing estimated to be $62 billion annually. As many as 87% of sepsis cases start in the community. According to the Sepsis Alliance, Mortality from sepsis increases 8% every hour that treatment is delayed. As many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment.

Sepsis testing and diagnosis can be viewed as a 2-stage process:

- Immediate patient testing and assessment focused on emergency treatment decisions, and
- Specific diagnosis of bacterial or fungal pathogen

The Nanomix S1 test panel focuses on the first phase, the need for rapid screening or patients suspected of sepsis. The S1 test panel provides an easy to use, rapid test at the first point of patient contact to deliver important information about the patient's condition. The panel includes Lactate, the current tool most used in sepsis screening, and adds two other tests (CRP and PCT) that are currently used to confirm a diagnosis. By using our multiplexing and multimodal technology, we are able to bring all three of these test results from a single sample to healthcare providers in an 11-minute test providing clinicians with host response diagnostics at the time of initial evaluation, in any care setting, may help assess the following questions and advance standards of care: 1) is there an infection or not? 2) is the infection viral or bacterial? 3) what is the severity and deficit of tissue perfusion?

Once hospitalized, a sepsis patient spends on average 8 days in an ICU. The S1 panel can also be used to monitor the progress of a patient and to support modification or discontinuation of antibiotic therapy.

Partnerships and Licensees

RedPharm (Beijing) Biotechnology Co., Ltd. (RedPharm) has the right to produce eLab cartridges for the S1 Assay panel in the PRC and has the right to sell and distribute the S1 Assay panel in the PRC, Japan, Korea, and countries in Southeast Asia.

Sales Channels

We recently established our sales and marketing function. We intend our products to be sold globally, both directly and through distributors, to hospitals and clinics, clinical laboratories, and other healthcare entities such as assisted living, extended care, and other non-hospital based care facilities. We have limited product distribution and our new sales and marketing team is working to build our product distribution capabilities in key markets such as North America, Europe, and Southeast Asia.

Currently RedPharm has rights to distribute our products in PRC, Japan, Korea, and countries in Southeast Asia and Medical Horizons has the rights to distribute in Italy. We are also actively developing distribution partners in the United Kingdom and European Union. To support our distributor's efforts, we plan to build a distribution sales and technical support capability within the company.

Manufacturing

We currently have limited manufacturing capacity for our consumable test cartridges and plan to implement automated production processes in the U.S. and bring on additional manufacturing resources to expand consumable test cartridge manufacturing capacity. We depend on several single source vendors to supply components for our disposable test cartridge and a US-based contract manufacturer for our eLab analyzer. We plan to bring on additional component suppliers to add supply chain capacity as well as backup. We have completed the purchase of a significant supply of printed electrodes from a former vendor and plan to qualify a new vendor of electrodes.

Sensor functionalization (converting raw electrodes into a biosensor) is currently done by Nanomix using a robotic system and final cartridge assembly is done by Nanomix manually. We plan to invest significantly in increasing capacity of sensor manufacturing processes and to automate portions of the cartridge assembly processes. The costs of our products are expected to decline significantly with volume growth as well as process automation.

RedPharm has the right to produce eLab cartridges in the PRC.

The Nanomix eLab analyzer is produced by a contract manufacturer located in the United States. While this is not an exclusive supply arrangement, it would be difficult to transfer production or add an additional supplier. The production of instruments is done on a purchase order basis. Nanomix purchases and consigns the materials for the quantity of instruments on the purchase order. The contract manufacturer builds, tests, and ships the units and invoices Nanomix based on the units shipped less the cost of the consigned materials. Some of the components used in the eLab analyzer have long lead times and Nanomix will purchase many of those components in quantities beyond the current purchase order.

Collaboration, License and Quality Agreements

To support the development and commercialization of our eLab system and products, in September 2017 we entered into a development and license agreement with RedPharm (Beijing) Biotechnology Co., Ltd., or the RedPharm License. Pursuant to the RedPharm License, we granted an exclusive license to the technology know-how, data and regulatory documents for our elab technology to RedPharm that will support the development of our elab analyzer in both humans and animals.

Under the agreement, RedPharm has the rights to produce the eLab cartridges in China for specific assays that are transferred by Nanomix to RedPharm. RedPharm is responsible for any clinical and regulatory activities necessary to register the products for sale in their territories. To date, Nanomix has transferred the S1 Critical Infections test to RedPharm and RedPharm has paid Nanomix $200 thousand in license fees related to the transfer of that specific assay. RedPharm is obligated to pay a royalty on the sales of S1 test cartridges.

RedPharm also has the rights to produce the eLab Analyzer in China for sale in the RedPharm territories upon the payment of an up front license fee. Each eLab analyzer placed by RedPharm with a customer carries a per unit royalty in the range of a low hundred dollars.

We retain exclusive rights to commercialize our products throughout the world, except in Australia, New Zealand, Singapore, China, Japan, Korea, Vietnam, Indonesia, Malaysia and the Philippines, where RedPharm will have exclusive rights to commercialize our elab technology. We retain rights to participate in the RedPharm markets depending on their progress in each of the countries. With RedPharm, we have established a collaboration for the management of the development of any product that utilizes our technology, including any joint, cross-territory studies that may be undertaken by the parties, if any.

Under the RedPharm License, RedPharm are obligated to pay us future milestone payments up to an aggregate of $6.4 million. Further, sales of test cartridges bear royalties of a low single-digit percentage based on net sales and sales of eLab Analyzers carry a per unit royalty in the low hundreds of dollars.

The RedPharm License continues in effect until the expiration of all payment obligations thereunder (including royalty payments and licensee revenue) on a product-by-product and country-by-country basis, unless earlier terminated by the parties. Pursuant to the terms of the RedPharm License, in addition to each party's right to terminate the agreement upon the other party's material breach (if not cured within a specified period after receipt of notice) or insolvency, (i) we also have unilateral termination rights in the event RedPharm commences any court action to invalidate any our intellectual property., and (ii) RedPharm has unilateral termination rights to cancel this agreement upon six (6) months prior written notice.

Technology & Development

Our products are based on the Nanomix eLab electrochemical detection technology. Current and planned products will operate on the eLab Analyzer using the current microfluidic disposable test cartridge form. New product development will be largely focused on expanding the menu of tests that operate on the eLab Analyzer. Our initial focus will be on testing for medical conditions that require rapid results for patient management and benefit from the mobile capabilities of our system. Future developments will expand the menu to tests that support other decentralized healthcare needs.

Competition

Many of our competitors are significantly larger and have greater financial, research, manufacturing, and marketing resources. Important competitive factors include product quality, performance, ease of use, price, customer service and reputation. Industry competition is based on these and the following additional factors:

- patent protection;
- technology expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and,
- ability to attract and retain qualified personnel.

We believe our technical capabilities and proprietary know-how relating to our eLab system are strong, particularly for the development of tests for critical care conditions in decentralized care environments. However, there are a number of competitive technologies used and/or seeking to be used by others in point-of-care settings.

Although we have no specific knowledge of any other competitors' products that could render our products obsolete, if we fail to maintain and enhance our competitive position or fail to introduce new products and product features, our customers may decide to use the products developed by our competitors, which could result in a loss of revenues and cash flow.

Employees

As of October 1, 2021, we had 25 full-time equivalent employees, of whom 3 were in administration, 11 in research and development and engineering, 8 in manufacturing and quality, and 3 in sales and marketing. The majority of our employees are located in Emeryville, California.

We have never had a work stoppage, and none of our employees are represented by a labor organization or subject to any collective bargaining arrangements. We consider our employee relations to be good.

Governmental Regulation

Certain of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of diagnostic products. Our clinical laboratory customers are subject to oversight by Centers for Medicare and Medicaid Services, or CMS, pursuant to CLIA, as well as agencies in various states. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil money penalties, injunctions, and criminal prosecution.

FDA Approval/Clearance Requirements

Unless an exemption applies, each medical device that we wish to market in the United States must receive 510(k) clearance or Premarket Approval (PMA). Medical devices that receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a PMA by the FDA are "approved" to market, distribute and sell in the United States. We cannot be certain that 510(k) clearance or PMA approval will ever be obtained for any products that we develop. Descriptions of the PMA and 510(k) clearance processes are provided below.

The FDA decides whether a device must undergo either the 510(k) clearance or PMA based on statutory criteria that utilize a risk-based classification system. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, in many cases, Class II medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The FDA uses these criteria to decide whether a PMA or a 510(k) is appropriate, including the level of risk that the agency perceives is associated with the device and a determination by the agency of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. In many cases, the FDA requires the manufacturer to submit a 510(k) requesting clearance (also referred to as a premarket notification), unless an exemption applies. The 510(k) must demonstrate that the manufacturer's proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device. A "predicate device" is a pre-existing medical device to which equivalence can be drawn, that is either in Class I or Class II or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application.

Device classification depends on the device's intended use and its indications for use. In addition, classification is risk-based, that is, the risk the device poses to the patient and/or the user is a major factor in determining the class to which it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) process.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) process. Pursuant to the Medical Device User Fee and Modernization Act of 2002, unless a specific exemption applies, 510(k) submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process.

Class III includes devices with the greatest risk. Devices in this class must meet all of the requirements in Classes I and II. In addition, Class III devices cannot be marketed until they receive Premarket Approval.

The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices require formal clinical studies to demonstrate safety and effectiveness. Under Medical Device User Fee and Modernization Act of 2002, PMA applications (and supplemental premarket approval applications) are subject to significantly higher user fees than 510(k) applications, and they also require considerably more time and resources.

510(k) Clearance Pathway

We are currently developing products that either will or are likely to require an FDA 510(k) clearance. We anticipate submitting a 510(k) for each such product to demonstrate that such proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a 510(k). The FDA's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases, the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, a PMA. The FDA requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a PMA, but the FDA can review any such decision and, if it disagrees with the manufacturer's determination, can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA of the modified device is obtained.

Clinical Laboratory Improvement Amendments of 1988

A manufacturer of a test categorized as moderately complex may request that categorization of the test be waived through a CLIA Waiver (CW) by Application submission to the FDA. When a test is categorized as waived, it may be performed by laboratories with a Certificate of Waiver, such as a physician's office or other outreach setting. In a CW submission, the manufacturer provides evidence to the FDA that a test meets the CLIA statutory criteria for waiver CLIA, a walk-in clinic or an emergency room provides CMS authority over all laboratory testing, except research that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group under the CMS, has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention or treatment of disease, or impairment of, or assessment of health. Under the CLIA program, unless waived, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections and pay fees. We anticipate requesting CLIA Waiver for the tests we develop.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our approved devices, including: the quality system regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures; the Medical Reporting Regulations, which require manufacturers to report to the FDA specified types of adverse events involving their products; labeling regulations; and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Some Class II devices are subject to special controls-such as performance standards, post-market surveillance, patient registries, and FDA guidelines-that do not apply to Class I devices.

The regulatory requirements that apply to our approved products classified as medical devices include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and,

- notices of corrections or removals.

Our Emeryville, CA facility is currently registered as an establishment with the FDA. We and any third-party manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with QSR and other regulations.

21st Century Cures Act

The 21st Century Cures Act, enacted in December 2016, contains several sections specific to medical device innovations. We believe that implementation of the 21st Century Cures Act may have a positive impact on its businesses by facilitating innovation and/or reducing the regulatory burden imposed on medical device manufacturers.

Environmental Laws

We believe that we are in compliance in all material respects with all foreign, federal, state, and local environmental regulations applicable to our manufacturing facilities. The cost of ongoing compliance with such regulations does not have a material effect on our operations.

Intellectual Property

Intellectual Property Strategy

Our intellectual property strategy is to: (1) build our own intellectual property portfolio around our eLab and electrochemical detection system; (2) pursue licenses, trade secrets and know-how within the area of rapid point-of-care testing; and, (3) develop and acquire proprietary positions to certain biomarkers.

eLab and Electrochemical Detection System Intellectual Property

We have obtained patent coverage on eLab and Electrochemical detection technology, including numerous patents in the United States, China, Japan, and the European Union. Additional patent applications are pending in the United States, as well as in the European Union.

Trademarks

We have filed and obtained trademarks for our products, including the Nanomix eLab System. Our trademarks have been obtained in the United States and certain other countries around the world.

Trade Secrets and Know-How

We have developed a substantial body of trade secrets and know-how relating to the development and manufacture of our eLab and electrochemical test system, including the production of sensors, the design and production of microfluidics contained in the disposable test cartridge, the sourcing and optimization of materials for such tests, and methods to maximize sensitivity, speed-to-result, specificity, stability and reproducibility of our tests. These trade secrets and know-how provide us with an important competitive advantage.

Properties

We do not own real properties. Our principal executive offices are located at 5900 Hollis Street, Emeryville, CA 94608. We lease our office pursuant to a lease which terminates on December 15, 2021. We believe that our existing facilities are suitable and adequate to meet our current needs. However, we will need to relocate the company to a new facility prior to the end of 2021 and we may add or expand as we increase production levels or add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's Consolidated Financial Statements. The Company does not believe that any of such pending claims and legal proceedings will have a material adverse effect on its Consolidated Financial Statements. The Company records a liability in its Consolidated Financial Statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary for its Consolidated Financial Statements not to be misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its Consolidated Financial Statements.

Set forth below is a description of the Company's Legal Proceedings.

In March 2019, we were served with notification of complaint filed by CureDM Inc. as agent for the members of CureDM Group Holdings, LLC filed with the Supreme Court of the State of New York County of New York regarding breach of contract and other matters relating to their desire to unwind the acquisition of CureDM Group Holdings LLC according to the original Contribution Agreement. The complaint was withdrawn by CureDM, Inc. in December 2019. The Company is continuing to work with the representatives from CureDM Inc. to settle this claim and unwind the Contribution Agreement.

In addition to the above matter, we are also in a dispute with Level Brands, Inc. regarding a License Agreement dated June 21, 2018 (JAMS Ref. No.: 1220061261). The Company filed an Answer to Complaint and Counter-complaint on June 25, 2019. Both parties are claiming non-performance under the License Agreement. The matter was scheduled for arbitration in October 2019. In October 2019, the arbitration was dismissed without prejudice.

On October 16, 2019 the Company received a Summons and Complaint filed by Microcap Headlines Inc. against the Company in the Supreme Court of the United States of New York County of Suffolk claiming damages of $18,000 and the costs and disbursements of the action. The Company filed an Answer on November 15, 2019. During January 2021, the Company settled this claim with Microcap Headlines, Inc. for $10,000 which was accrued on the Company's balance sheet at December 31, 2020.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included herein, including our financial statements and related notes, before deciding whether to invest in our securities. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Additional Capital

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

The COVID-19 pandemic, the measures attempted to contain and mitigate the effects of the virus, including travel bans and restrictions, shelter-in-place, quarantine and other similar governmental orders and restrictions on trade put in place around the world have caused widespread disruption in global economies, productivity and financial markets and have materially altered the way in which we conduct our day-to-day business.

The full extent to which the COVID-19 pandemic and the various responses to it impact our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic, including any potential future waves of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the effect on players and their willingness and ability to pay entry fees for the games on our platform; the effect on our third party developers and their willingness and ability to engage with our services and our platform; disruptions or restrictions on our employees' ability to work and travel; and interruptions related to our cloud networking and platform infrastructure and partners, and developer and user service and support providers. As the COVID-19 pandemic continues, we may not be able to provide the same level of services and support that our developers and players expect from us, which could negatively impact our business and operations. While substantially all of our business operations can be performed remotely, many of our employees are juggling additional work-related and personal challenges, including adjusting communication and work practices to collaborate remotely with work colleagues and business partners, managing technical and communication challenges of working from home on a daily basis, looking after children as a result of remote-learning and school closures, making plans for childcare and caring for themselves, family members or other dependents who are or may become ill. We will continue to actively monitor the issues raised by the COVID-19 pandemic and may take further actions that alter our business operations, including as may be required by federal, state, local or foreign authorities or that we determine are in the best interests of our employees, players, partners, game developers and stockholders.

The COVID-19 pandemic and resulting shelter-in-place, quarantine and other similar governmental orders and restrictions have also led to increased player engagement with the games on our platform relative to historic trends. These increases in player activity may not be indicative of our financial and operating results in future periods. The long-term effects of the COVID-19 pandemic on society and player behavior are highly uncertain, and there is no assurance that player engagement will not decrease, as the full impacts of the pandemic on society and the global economy become more clear.

In addition to the potential direct impacts to our business, the U.S. economy has been, and is likely to continue to be, significantly weakened as a result of the actions taken in response to COVID-19. A weakened U.S. economy may impact our third-party developers and players and their engagement with our platform, and the ability of our business partners to navigate this complex social health and economic environment, any of which could result in disruption to our business and results of our operations.

The duration and extent of the impact from the COVID-19 pandemic depends on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, the existence of any additional waves of the pandemic, the extent and effectiveness of containment actions, treatment and prevention measures, including vaccines, and the impact of these and other factors on our employees, third-party developers, players and other business partners. If we are not able to respond to and manage the impact of such events effectively, our business may be harmed.

We have incurred significant losses since inception and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability.

We have incurred significant losses since inception through December 31, 2020 and expect to incur losses in the future. Our accumulated deficit as of June 30, 2021 and December 31, 2020 was approximately $102.1 million and $97.3 million, respectively, and we incurred net losses each year since inception. We expect that our losses may continue for at least the next few years as we will be required to invest significant additional funds toward the continued development and commercialization of our technology. Our ability to achieve or sustain profitability depends on numerous factors, many of which are beyond our control, including the market acceptance of our products and future product candidates, future product development, our ability to achieve marketing clearance from the FDA and international regulatory clearance for future product candidates, our ability to compete effectively against an increasing number of competitors and new products, and our market penetration and margins. In spite of efforts to ramp sales of our products, we may never be able to generate sufficient revenue to achieve or sustain profitability.

Our financial situation creates doubt whether we will continue as a going concern.

We have not generated substantial revenues to date. For the years ended December 31, 2020 and 2019, the Company had loss of $6.2 million and $5.5 million, respectively. For the six months ended June 30, 2021, the Company had a net loss of approximately $4.8 million. There can be no assurances that we will be able to achieve a level of revenues adequate to generate sufficient cash flow from operations or additional financing through private placements, public offerings and/or bank financing necessary to support our working capital requirements. To the extent that funds generated from any private placements, public offerings and/or bank financing are insufficient, we will have to raise additional working capital. No assurance can be given that additional financing will be available, or if available, will be on acceptable terms. These conditions raise substantial doubt about our ability to continue as a going concern. If adequate working capital is not available, we may be forced to discontinue operations, which would cause investors to lose their entire investment. Our auditors have indicated that these conditions raise substantial doubt about the Company's ability to continue as a going concern.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We will need to continue to seek capital from time to time to continue development of our advanced mobile POC diagnostic system and to acquire and develop other products. Once approved for commercialization, we cannot provide any assurances that any revenues it may generate in the future will be sufficient to fund our ongoing operations. We expect that our current cash position will be sufficient to fund our current operations for at least the next 4 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of

such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities may dilute our existing stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our inability to raise capital on acceptable terms in the future may cause us to delay, diminish, or curtail certain operational activities as we have done during the fiscal year ended December 31, 2020, including research and development activities, sales and marketing, and other operations, in order to reduce costs and sustain the business, and such inability would have a material adverse effect on our business and financial condition.

We expect capital outlays and operating expenditures to increase over the next several years as we work to expand our commercial activities, expand our development activities, expand manufacturing operations and expand our infrastructure. We may need to raise additional capital to, among other things:

- sustain and expand the commercialization of our FDA cleared and commercialized assays and assays under development or review by the FDA;
- expand and automate our manufacturing capabilities and reduce our cost of sales;
- increase our sales and marketing efforts to drive market adoption and address competitive developments;
- finance capital expenditures and our general and administrative expenses;
- develop new assays;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems; and
- hire additional research and development, quality control, scientific, and general and administrative personnel.

Our present and future funding requirements will depend on many factors, including but not limited to:

- the progress and timing of our clinical trials;
- the level of research and development investment required to maintain and improve our technology position;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, if any;
- our efforts to acquire or license complementary technologies or acquire complementary businesses;
- changes in product development plans needed to address any difficulties in commercialization or changing market conditions;
- competing technological and market developments;
- changes in regulatory policies or laws that may affect our operations; and
- changes in physician acceptance or medical society recommendations that may affect commercial efforts.

Raising additional capital will cause dilution to our existing stockholders and may restrict our operations or require us to relinquish certain intellectual property rights.

We will seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances, licensing arrangements and grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders may be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt and receivables financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. A failure to obtain adequate funds may cause us to curtail certain operational activities, including research and development, regulatory trials, sales and marketing, and manufacturing operations, in order to reduce costs and sustain the business, and would have a material adverse effect on our business and financial condition.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on regulatory approvals of our diagnostic tests. In the past, life science companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. Additionally, due to our price volatility and our high demand for cash to fund operations, we have had to conduct a number of reverse stock splits and highly dilutive financings to continue as a going concern which exposes us to additional risk of securities class action litigation. 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 and result in a decline in the market price of our common stock. If such lawsuits were successful we

may not be able to pay awarded damages and we may be forced into bankruptcy which would likely result in the complete loss of your investment.

Market and economic conditions may negatively impact our business, financial condition and share price.

In recent years, concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and unstable or unpredictable economic and market conditions. If these conditions occur, deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current and future service providers, manufacturers, suppliers, hospitals and other medical facilities, our third party payors, and other partners could be negatively affected by these difficult economic times, which could adversely affect our ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

The small size of the Company's accounting staff has limited segregation of financial duties which could result in material misstatements in our financial statements in future periods.

The Company's CEO and Controller have identified control deficiencies regarding the lack of segregation of duties and the need for a stronger internal control environment. The small size of the Company's accounting staff may prevent adequate controls in the future, such as segregation of duties, due to the cost/benefit of such remediation.

Although the Company has hired a Controller to work on SEC reporting and accounting matters, we expect that the Company will need to hire accounting personnel with the requisite knowledge to improve the levels of review of accounting and financial reporting matters. The Company may experience delays in doing so and any such additional employees would require time and training to learn the Company's business and operating processes and procedures. For the near-term future, until such personnel are in place, this will continue to be a weakness in the Company's internal control over financial reporting that could result in material misstatements in the Company's financial statements not being prevented or detected.

In addition, other control weaknesses or deficiencies may be identified in the future. If we are unable to correct such weaknesses or deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC will be adversely affected, and could result in material misstatements in our financial statements in future periods. This failure could negatively affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

Risks Related to the Private Placement

Our obligations to the holders of our Notes are secured by a security interest in substantially all of our assets, so if we default on those obligations, the note holders could foreclose on our assets.

Our obligations under the Notes are secured by a security interest in substantially all of our assets. As a result, if we default in our obligations under the Notes, the holders of the notes, acting through their appointed agent, could foreclose on their security interests and liquidate some or all of these assets, which would harm our business, financial condition and results of operations and could require us to curtail or cease operations.

If the holders of our Notes elect to convert the principal and interest due under the Notes, our stockholders will experience substantial dilution in their investment.

The total remaining principal amount we owe to the holders of our Notes is approximately $8.4 million as of September 30, 2021. If the holders of these Notes were to elect to convert all of the principal amount (and assuming no interest has accrued on the principal amount) into shares of our common stock at the Conversion Price of $2.0587, we would be required to issue approximately 7.2 million shares. These conversions would result in significant dilution to the investments of our existing stockholders.

The holders of our Notes have certain rights upon an event of default under the Notes which could harm our business, financial condition and results of operations and could require us to curtail or cease or operations.

Under our Notes, the holders of the Notes may require us to redeem all or any portion of the Notes (including all accrued and unpaid interest thereon), in cash, at a price equal to the greater of (i) 115% of the amount to be redeemed and (ii) the product of (X) the Conversion Rate (as defined in the Notes) multiplied by (Y) the product of (1) 120% multiplied by (2) the greatest Closing Sale Price of the Common Stock on any Trading Day during the period commencing on the Trading Day immediately preceding such Event of Default (or deemed Event of Default disregarding any cure period in such Event of Default above) and ending on the date the Company makes the entire payment required to be made. It is unlikely that we would have the cash to redeem the Notes as required. Furthermore, if we default on the payment of the notes, interest on the notes will accrue at the rate of 18% per annum. If we were unable to come to an agreement with the holders of the Notes regarding payment, the holders could foreclose on their security interest, which could harm our business, financial condition and results of operations and could require use to curtail or cease our operations.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

If we cannot successfully develop, maintain, commercialize, or obtain regulatory approvals for new and existing diagnostic assays, our financial results will be harmed and our ability to compete will be harmed.

Our financial performance depends in part upon our ability to successfully develop and market new assays in a rapidly changing technological and economic environment, and to maintain and successfully commercialize previously cleared assays. If we fail to successfully introduce new assays or do not maintain approval for previously FDA-cleared assays, we could lose customers and market share. We could also lose market share if our competitors introduce new assays or technologies that render our assays less competitive or obsolete. In addition, delays in the introduction of new assays due to regulatory, developmental or other obstacles could negatively impact our revenue and market share, as well as our earnings. Factors that can influence our ability to introduce new assays, the timing associated with new product approvals and commercial success of these assays include:

- the scope of and progress made in our research and development activities;

- our ability to successfully initiate and complete clinical trial studies;
- timely expansion of our menu of assays;
- the results of clinical trials needed to support any regulatory approvals of our assays;
- our ability to obtain and maintain requisite FDA or other regulatory clearances or approvals for our assays on a timely basis;
- demand for the new assays we introduce;
- product offerings from our competitors; and
- the functionality of new assays that address market requirements and customer demands.

We are subject to many laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.

The assays that we develop and commercialize in the future are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our assays. In particular, FDA regulations govern activities such as product development, product testing, product labeling, product storage, premarket clearance or approval, manufacturing, advertising, promotion, product sales, reporting of certain product failures and distribution. Our assays will require 510(k) clearance from the FDA prior to marketing.

We may be unable to obtain marketing clearance for our assays in development. If such approval is obtained, it may:

- take a significant amount of time;
- require the expenditure of substantial resources;
- involve stringent clinical and pre-clinical testing;
- involve modifications, repairs, or replacements of our assays; and/or
- result in limitations on the proposed uses of our assays.

Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, refuse to grant pending pre-market approval applications or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a company-wide basis, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our diagnostic tests.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to more rigorous regulation by foreign governmental authorities in the future. Penalties for a company's non-compliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and criminal sanctions. Any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on us.

Our current and potential customers in the United States and elsewhere may also be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

The life sciences industry is highly competitive and subject to rapid technological change. If our competitors and potential competitors develop superior assays and technologies, our competitive position and results of operations would suffer.

We face intense competition from a number of companies that offer assays in our target markets, many of which have substantially greater financial resources and larger, more established marketing, sales and service operations than we do. The life sciences industry is characterized by rapid and continuous technological innovation. We may need to develop new technologies for our existing product and our assays to be competitive. One or more of our current or future competitors could render our existing products or assays under development obsolete or uneconomical by technological advances. We may also encounter other problems in the process of delivering new assays to the marketplace, such as problems related to FDA clearance or regulations, design, development or manufacturing of such assays, and as a result we may be unsuccessful in selling such assays. Our future success depends on our ability to compete effectively against current technologies, as well as to respond effectively to technological advances by developing and marketing assays that are competitive in the continually changing technological landscape.

If our assays do not perform as expected or the reliability of the technology on which our assays are based is questioned, we could experience delayed or reduced market acceptance of our assays, increased costs and damage to our reputation.

Our success depends on the market's confidence that we can provide reliable, high-quality analyzers and diagnostic program. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our assays or technologies may be impaired if our assays fail to perform as expected or our assays are perceived as difficult to use. Despite quality control testing, defects or errors could occur in our assays or technologies.

In the future, if our assays experience a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, product recalls, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our assays, either of which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any widespread concerns regarding our technology or any manufacturing defects or performance errors in our assays could result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

COVID-19 diagnostic tests are subject to changes in CLIA, FDA, and other regulatory requirements.

Our COVID-19 tests are subject to regulations of the FDA, International Organization for Standards and other regulatory requirements. The regulations regarding the manufacture and sale of COVID-19 tests may be unclear and are subject to change. Newly promulgated regulations could require changes to our COVID-19 diagnostic tests, necessitate additional procedures, or make it impractical or impossible for us to market our tests for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to impose new or additional requirements relating to COVID-19 tests. The implementation of such changes or new or additional requirements may result in substantial additional costs and could delay or make it more difficult or complicated to sell our products. Further, our COVID-19 tests, if approved, will be marketed under an Emergency Use Authorization (EUA) from the FDA. The FDA may decide to withdraw EUA designation for the SARS CoV-2 pandemic, resulting in the need for us to apply for clearance to market under a 510(k) or other regulatory process. This could result in substantial additional costs and time to develop the necessary data and information for such clearance.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, authorized, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear, approve, or authorize new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for medical devices or modifications to be cleared or approved, medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If our COVID-19 Antigen Panel, our COVID-19 IgG/IgM Antibody panel, our S1 Assay Panel products or any of our other product candidates fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our growth prospects, operating results and financial condition may be harmed.

The commercialization of our COVID and S1 Assay Panel products and the future commercialization of our other product candidates in the United States and other jurisdictions in which we intend to pursue marketing clearance are key elements of our strategy. If we are not successful in conveying to hospitals and other customers that our current products and future product candidates provide equivalent or superior diagnostic information in a shorter period of time compared to existing technologies, or that these products and future product candidates improve patient outcomes or decrease healthcare costs, we may experience reluctance, or refusal, on the part of hospitals to order, and third-party payors to pay for performing a test in which our product is utilized.

These hurdles may make it difficult to demonstrate to hospitals and other healthcare providers that our current diagnostic products and future product candidates are appropriate options for testing, may be superior to available tests and may be more cost-effective than alternative technologies.

If we fail to successfully commercialize our products and product candidates, we may never receive a return on the significant investments in product development, sales and marketing, regulatory, manufacturing and quality assurance we have made and further investments we intend to make and may fail to generate revenue and gain economies of scale from such investments.

If any of our products, or the malfunctioning of our products, causes or contributes to a death or a serious injury, 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 has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our assays could also 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 assays may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, including a third-country authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our international distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our assays would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, it could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they occur.

We are also required to follow detailed recordkeeping requirements for all Company-initiated medical device corrections and removals. In addition, in December 2012, the FDA issued a draft guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device that addresses a violation of the FDCA, that change would generally constitute a medical device recall and require submission of a recall report to the FDA.

If we become subject to claims relating to improper handling, storage or disposal of hazardous materials, we could incur significant cost and time to comply.

We are subject to foreign, federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, or OSHA, and the Environmental Protection Agency, or EPA, and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. OSHA or the EPA may adopt additional regulations in the future that may affect our research and development programs. The risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

Our diagnostic products have not been manufactured in significant volume and are subject to unforeseen scale-up risks.

Although we have developed a process to manufacture our diagnostic products, there can be no assurance that we can manufacture our diagnostic products at a scale that is adequate for our future commercial needs. We may face significant or unforeseen difficulties in manufacturing our diagnostic products, including but not limited to:

- technical issues relating to manufacturing components of our diagnostic products on a high volume commercial scale at reasonable cost, and in a reasonable time frame;
- difficulty meeting demand or timing requirements for orders due to excessive costs or lack of capacity for part or all of an operation or process;
- lack of skilled labor or unexpected increases in labor costs needed to produce or maintain our analyzers or perform certain required operations;
- changes in government regulations or in quality or other requirements that lead to additional manufacturing costs or an inability to supply product in a timely manner, if at all; and
- increases in raw material or component supply cost or an inability to obtain supplies of certain critical components or supplies needed to complete our manufacturing processes.

These and other difficulties may only become apparent when scaling up to the manufacturing process of our diagnostic products to a more substantive commercial scale. If our diagnostic products cannot be manufactured in sufficient commercial quantities or manufacturing is delayed, our future prospects could be significantly impacted and our financial prospects would be materially harmed.

We or our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing of our diagnostic products that could result in delays or shortfalls in our production. Our suppliers may also face similar delays or shortfalls. In addition, our or our suppliers' production processes may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our or our suppliers' manufacturing costs, delay production of our diagnostic products, reduce our product gross margin and adversely impact our business. If we are unable to satisfy demand for our diagnostic products by successfully manufacturing and shipping our diagnostic products in a timely manner, our revenue could be impaired, market acceptance for our assays could be adversely affected and our customers might instead purchase our competitors' assays. In addition, developing manufacturing procedures for assays under development may require developing specific production processes for those assays. Developing such processes could be time consuming and any unexpected difficulty in doing so can delay the introduction of a product.

We utilize third-party, single-source suppliers for some components and materials used in our products and product candidates, and the loss of any of these suppliers could have an adverse impact on our business.

We rely on single-source suppliers for some components and materials used in our products and product candidates. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these components in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. While our suppliers have generally met our demand for their products on a timely basis in the past, these were with limited production quantities and we cannot assure that they will in the future be able to meet our demand for their products, either because we do not have long-term agreements with those suppliers, our relative importance as a customer to those suppliers, or their ability to produce the components used in our products. For example, our supplier of printed electrodes has exited the printing business. We purchased safety stock from the supplier prior to their discontinuing production and have begun qualification of a replacement supplier.

While we believe replacement suppliers exist for all components and materials we obtain from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we will seek to maintain adequate inventory of the single-source components and materials used in our products in the event of disruption, those inventories may not be sufficient.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on our business.

Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

Our business strategy depends on our ability to manufacture and assemble our current and proposed products in sufficient quantities and on a timely basis to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;

- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to build production lines to enable us to efficiently produce products; and
- difficulty identifying and qualifying alternative suppliers for components in a timely manner.

As demand for our products increases, we will need to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and implement manufacturing and quality systems. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, while we expect most new products will utilize the eLab instrument system and existing consumable cartridge, manufacturing of future products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable. Any future interruptions we experience in the manufacturing or shipping of our products could delay our ability to recognize revenues in a particular quarter and could also adversely affect our relationships with our customers.

We expect to rely on third parties to conduct studies of our assays under development that will be required by the FDA or other regulatory authorities and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the field trial studies or other studies that may be required to obtain FDA and other regulatory clearances or approvals for our assays. Accordingly, we expect to rely on third parties, such as independent testing laboratories and hospitals, to conduct such studies. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for additional assays.

Any clinical trials that we may conduct may not begin on time, or at all, may not be completed on schedule, or at all, or may be more expensive than we expect, which could prevent or delay regulatory approval of our assays or impair our financial position.

The commencement or completion of any clinical trials that we may conduct may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities suspend or place on hold a clinical trial, or do not approve a clinical trial protocol or a clinical trial;
- the data and safety monitoring committee or applicable hospital institutional ethics review board recommends that a trial be placed on hold or suspended;
- fewer patients meet our clinical study criteria and our enrollment rate is lower than we expected;
- clinical trial sites decide not to participate or cease participation in a clinical trial;
- third-party clinical investigators do not perform our clinical trials on schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- we fail regulatory inspections of our manufacturing facilities requiring us to undertake corrective action or suspend or terminate our clinical trials;
- interim results of the clinical trial are inconclusive or negative;
- pre-clinical or clinical data are interpreted by third parties in unanticipated ways; or
- our trial design is inadequate to demonstrate safety and/or efficacy.

Our clinical trial costs will increase if we have material delays in those trials or if we need to perform more or larger trials than planned. Adverse events during a clinical trial could cause us to repeat a trial, terminate a trial or cancel an entire program. Should our clinical development plan be delayed, this could have a material adverse effect on our operations and financial condition.

Product liability claims could adversely impact our financial condition and our earnings and impair our reputation.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. Device failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks or product-related information with respect to our assays could result in an unsafe condition regarding, injury to, or death of, a patient. The occurrence of such a problem could result in product liability claims or a recall of, or safety alert relating to, one or more of our assays. Product liability claims or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers for our assays.

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

Our future success will depend on the market's confidence that our technologies can provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in our products. If our technology fails to perform a clinical test, then we could face claims against us or our reputation could suffer as a result of such failures. The failure of our current products or planned diagnostic product candidates to perform reliably or as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors.

Our products may not be able to compete with new diagnostic products or existing products developed by well-established competitors, which would negatively affect our business.

The diagnostic industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. Important

competitive factors for our products include price, quality, performance, ease of use, and customer service.

A few large corporations produce a wide variety of diagnostic tests and other medical devices and equipment. A larger number of mid-size companies generally compete only in the diagnostic industry and a significant number of small companies produce only a few diagnostic products. As a result, the diagnostic test industry is highly fragmented and segmented.

Some of our principal competitors may have considerably greater financial, technical and marketing resources than we do. Several companies produce diagnostic tests that compete directly with our testing product line, including Abbott (Alere), Siemens, Becton Dickinson, and Danaher. Some competitors offer broader product lines and may have greater name recognition than we have. These and other companies have or may have products incorporating advanced technologies that over time could directly compete with our testing product line.

As new products incorporating new technologies enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold. If our competitors' products take market share from our products through more effective marketing or competitive pricing, our revenues, margins and operating results could be adversely affected.

Our future revenues and operating results may be negatively affected by ongoing consolidation in the healthcare industry

There has been a significant amount of consolidation in the healthcare industry. This consolidation has increased the competition to provide goods and services to customers. In addition, group purchasing organizations and integrated health delivery networks have served to concentrate purchasing decisions for some customers, which has also placed pricing pressure on medical device suppliers. Due to ongoing consolidation, there could be additional pressure on the prices of our products.

Undetected errors or defects in our products or product candidates could harm our reputation, decrease market acceptance of our products or expose us to product liability claims.

Our products or product candidates may contain undetected errors or defects. Disruptions or other performance problems with our products or product candidates may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to errors or defects in our products or product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products or product candidates could harm our business and operating results.

The sale and use of products or product candidates or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We currently develop, manufacture and test our products and product candidates and some of their components in a single facility. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently develop, manufacture and test our products and product candidates exclusively in a facility in Emeryville, California. If this or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if our business is disrupted for any other reason, we may not be able to develop or test our products and product candidates as promptly as our potential customers expect, or possibly not at all.

The manufacture of components of our products and product candidates involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected.

The Sublease for our current facility expires in December 2021. We will need to identify, contract, and relocate our operations to a new location. Moving our manufacturing and development facility may interrupt our business resulting in higher costs and potentially lost revenue.

We maintain insurance coverage against damage to our property and equipment, subject to deductibles and other limitations that we believe is adequate. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

Third-Party reimbursement policies and potential cost constraints could negatively affect our business.

The list of our product end-users includes hospitals and other healthcare providers. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

Hospitals and other healthcare providers who purchase diagnostic products in the United States generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Due to the overall escalating cost of medical products and services, there is increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis.

Ongoing changes in healthcare regulation could negatively affect our revenues, business and financial condition.

There have been several proposed changes in the United States at the federal and state level for comprehensive reforms regarding the payment for, the availability of and reimbursement for healthcare services. These proposals have ranged from fundamentally changing federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs. One example is the Patient Protection and Affordable Care or the Affordable Care Act, the Federal healthcare reform law enacted in 2010.

Healthcare reform initiatives will continue to be proposed and may reduce healthcare related funding in an effort. It is impossible to predict the ultimate content and timing of

any healthcare reform legislation and its resulting impact on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise negatively effect on our financial condition and results of operations.

In April 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the European Union Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area, which we refer to as the EEA, member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will, however, only become fully applicable three years after publication (in May 2020). Once applicable, the Medical Devices Regulation will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Expected to be implemented in 2022, the Medical Devices Regulation may impose increased compliance obligations for us to access the EU market.

Legislative and other regulatory changes could have an effect on our business.

Changes in regulatory or economic conditions or in the laws and policies governing foreign trade, taxes, manufacturing, and development in the United States could impact our business. Economic and regulatory changes could also affect foreign currency exchange rates which, in turn, could affect our reported financial results and our competitiveness on a worldwide basis.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

Many healthcare companies, including healthcare systems, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for diagnostic tests. If we are forced to reduce our prices because of consolidation in the healthcare industry, our projected revenues would decrease and our earnings, financial condition, and/or cash flows would suffer.

If we or our distributors do not comply with the U.S. federal and state fraud and abuse laws, including anti-kickback laws for any products approved in the U.S., or with similar foreign laws where we market our products, we could face significant liability.

There are numerous United States federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, false claims, and physician transparency laws. Our relationships with physicians and surgeons, hospitals and our independent distributors are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including significant fines, damages and monetary penalties and in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- federal civil False Claims Act prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009, which, among other things, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- HIPAA also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the federal Foreign Corrupt Practices Act of 1997, which makes it illegal to offer or provide money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage; and

- state 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, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. Some states, such as California, Massachusetts, Nevada, and Vermont mandate implementation of commercial compliance programs and/or impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to physicians.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with the DOJ or other law enforcement agencies have forced healthcare providers to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could have a material adverse effect on our reputation, business and financial condition.

Many foreign countries have enacted similar laws addressing fraud and abuse in the healthcare sector. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance requirements in multiple jurisdictions increases the possibility that we may run afoul of one or more of the requirements.

If we are unable to recruit, train and retain key personnel, we may not achieve our goals.

Our future success depends on our ability to recruit, develop, retain and motivate key personnel, including individuals for our senior management, research and development, engineering, manufacturing and sales and marketing teams. Additionally, we will need to hire a Chief Financial Officer and other financial personnel in the future. We do not have employment contracts with management personnel. Competition for qualified personnel is intense, particularly in the San Francisco Bay area. Our growth depends on attracting, retaining and motivating highly skilled personnel with the necessary technical or scientific background and ability to understand our products at a technical and clinical level. In addition, we will need to hire automation engineers and other manufacturing employees to meet demand for our products as we scale up our sales and marketing operations. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract, develop, retain and motivate qualified personnel could materially harm our operating results and growth prospects.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our financial condition and results of operations.

We are subject to income taxes as well as non-income based taxes in both the United States and various foreign jurisdictions. Changes in existing tax laws, treaties, regulations or policies or the interpretation or enforcement thereof, or the enactment or adoption of new tax laws, treaties, regulations or policies could materially impact our effective tax rate.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and prospects will be harmed.

If we are unable to obtain or sustain adequate revenue growth, our financial results could suffer. Furthermore, significant growth will place strains on our management and our operational and financial systems and processes and our operating costs may escalate even faster than planned. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace. Additionally, if we do not successfully forecast the timing of regulatory authorization for our additional tests, marketing and subsequent demand for our diagnostic tests or manage our anticipated expenses accordingly, our operating results will be harmed.

Other companies or institutions have commercial assays or may develop and market novel or improved methods for infectious disease diagnostics, which may make our diagnostic platform less competitive or obsolete.

The market for diagnostics is large and established, and our competitors may possess significantly greater financial resources and have larger development and commercialization capabilities than we do. We may be unable to compete effectively against these competitors either because their diagnostic platforms are superior or because they may have more expertise, experience, financial resources or stronger business relationships.

New technologies, techniques or assays could emerge that might offer better combinations of price and performance than our current or future assays.

It is critical to our success that we anticipate changes in technology and customer requirements and to successfully introduce, on a timely and cost-effective basis, new, enhanced and competitive technologies that meet the needs of current and prospective customers. If we do not successfully innovate and introduce new technology into our product lines or manage the transitions to new product offerings, our revenues, results of operations and business will be adversely impacted. Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved diagnostic tests and as new companies enter the market with new technologies.

We could be exposed to liability if we experience security breaches or other disruptions, which could harm our reputation and business

We may be subject to cyber-attacks whereby computer hackers may attempt to access our computer systems or our third-party IT service provider's systems and, if successful, misappropriate personal or confidential information. In addition, a contractor or other third party with whom we do business may attempt to circumvent our security measures or obtain such information and may purposefully or inadvertently cause a breach involving sensitive information. We will continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, but cyber-attacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Even though we take cyber-security measures that are continuously reviewed and updated, our information technology networks and infrastructure may still be vulnerable due to sophisticated attacks by hackers or breaches.

Even the most well protected IT networks, systems, and facilities remain potentially vulnerable because the techniques used in security breaches are continually evolving and generally are not recognized until launched against a target and, in fact, may not be detected. Any such compromise of our or our third party's IT service providers' data security and access, public disclosure, or loss of personal or confidential business information, could result in legal claims proceedings, liability under laws to protect, privacy of personal information, and regulatory penalties, disrupt our operations, require significant management attention and resources to remedy any damages that result, damage our reputation and customers willingness to transact business with us, any of *which could adversely affect our business.*

We expect to generate a portion of our revenue internationally and are subject to various risks relating to those international activities which could adversely affect our operating results.

A portion of our revenue is expected to come from international sources. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights; and
- pandemics and public health emergencies, such as the coronavirus (COVID-19), could result in disruptions to travel and distribution in geographic locations where our products are sold.

As we expand internationally, our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in U.S. dollars. If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

Our employees, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners, distributors and vendors. Misconduct by these parties could include intentional, reckless or negligent failures to: comply with the regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity 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 comply with these 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business.

We have limited experience in marketing and selling our products, and if we are unable to expand, manage and maintain our direct sales and marketing organizations, or otherwise commercialize our products, our business may be adversely affected.

Because we received CE-mark for our S1 Assay Panel in November of 2019 and began commercial sales activities in September 2020, we have limited experience marketing and selling our products. We began staffing our sales and marketing organization in 2021 and currently have a staff of 3. Our financial condition and operating results will be highly dependent upon the efforts of our sales and marketing organization. If we are unable to quickly build our sales and marketing team or if our sales and marketing efforts fail to adequately promote, market and sell our products, our sales may not increase at levels that are in line with our forecasts.

Our future sales growth will depend in large part on our ability to successfully build and expand the size and geographic scope of our sales and marketing team. Accordingly, our future success will depend largely on our ability to hire, train, retain and motivate skilled sales and marketing personnel. Because the competition for individuals with their skillset is high, there is no assurance we will be able to hire and retain personnel on commercially reasonable terms. If we are unable to build and expand our sales and marketing capabilities, we may not be able to effectively commercialize our products and our business and operating results may be adversely affected. Additionally, we will need to implement management information systems to support the sales and marketing operations. There is no assurance that these systems will be implemented and effective. Lack of these management information systems may negatively impact sales efforts.

Outside of the United States, we will sell our products through distribution partners and there is no guarantee that we will be successful in attracting or retaining desirable distribution partners for these markets or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products effectively or may choose to favor marketing the products of our competitors. If distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize our sales growth.

Our ability to grow our business will be limited if we fail to develop and maintain new and existing distribution channels.

Our plan to grow our business depends on third parties and distributors to sell our products. The sale of our products depends in large part on our ability to sell products to these customers and on the marketing and distribution abilities of the companies with which we collaborate.

Reliance on distributors and third-parties to market and sell our products could negatively impact our business for various reasons, including: (i) we may not be able to find suitable distributors for our products on satisfactory terms, or at all; (ii) agreements with distributors may prematurely terminate or may result in litigation between the parties; (iii) our distributors or other customers may not fulfill their contractual obligations and distribute our products in the manner or at the levels we expect; (iv) our distributors may prioritize other products or their own private label products that compete with our products; (v) Our existing distributor relationships or contracts may preclude or limit us from entering into arrangements with other distributors; and (vi) we may not be able to negotiate new or renew existing distribution agreements on acceptable terms, or at all.

We will try to maintain and expand our business with distributors and third parties and make every effort to require that they fulfill their contractual obligations, but there can be no assurance that such companies will do so or that new distribution channels will be available on satisfactory terms. If we are unable to do so, our business will be negatively impacted.

Potential customers may not adopt rapid Point-of-Care diagnostic testing.

Rapid point-of-care tests are beneficial because, among other things, they can be administered by healthcare providers in their own facilities or used by healthcare facilities without sending samples to central laboratories. But currently the majority of diagnostic tests used by healthcare providers in the U.S. are provided by clinical reference laboratories and hospital-based laboratories. In some international markets, such as Europe, diagnostic testing is performed primarily by centralized laboratories. Future sales of our products will depend, in part, on our ability to expand market acceptance of rapid point-of-care testing and successfully compete against laboratory testing methods and products. However, we expect that clinical reference and other hospital-based laboratories will continue to compete vigorously against our rapid point-of-care products. Even if we can demonstrate that our products are more cost effective, save time, or have better performance or other benefits, healthcare providers may resist changing to rapid point-of-care tests and instead may choose to obtain diagnostic results through laboratory tests. If we fail to achieve and expand market acceptance of our rapid point-of-care diagnostic tests with customers, it would have a negative effect on our future sales growth.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from their sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;

- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenues and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization for that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the drug. If the FDA or applicable foreign regulatory agency concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the regulatory agencies will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The regulatory agencies may also require a REMS for an approved product when new safety information emerges. Any of

these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Adverse events involving our products may lead the FDA or applicable foreign regulatory agency to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results.

Once a product receives regulatory clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on a regulatory finding that there is a reasonable probability that the product would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The regulatory agencies require that certain classifications of recalls be reported to them within ten (10) working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the regulatory agency. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the regulatory agencies. If the regulatory agency disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the regulatory agency could take enforcement action for failing to report the recalls when they were conducted.

The in-licensing of technologies and the successful testing and early development of technologies in the laboratory may not be indicative of future results and may not result in commercially viable technologies or products. Further, our future products may have to be modified from their originally conceived versions in order to reach or be successful in the market.

Positive results from laboratory testing and early developmental successes, may not be predictive of future successful development, commercialization and sales results and should not be relied upon as evidence that products developed from our technologies will become commercially viable and successful. Further, the products we plan to develop in the future may have to be significantly modified from their originally conceived versions in order for us to control costs, compete with similar products, receive market acceptance, meet specific development and commercialization timeframes, avoid potential infringement of the proprietary rights of others, or otherwise succeed in developing our business and earning ongoing revenues. This can be a costly and resource draining activity. What appear to be promising technologies when we license them may not lead to viable technologies or products, or to commercial success.

We utilize third-party, single-source suppliers for some components and materials used in our products and product candidates, and the loss of any of these suppliers could have an adverse impact on our business.

We rely on single-source suppliers for some components and materials used in our products and product candidates. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these components in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. While our suppliers have generally met our demand for their products on a timely basis in the past, these were with limited production quantities and we cannot assure that they will in the future be able to meet our demand for their products, either because we do not have long-term agreements with those suppliers, our relative importance as a customer to those suppliers, or their ability to produce the components used in our products. For example, our supplier of printed electrodes has exited the printing business. We purchased safety stock from the supplier prior to their discontinuing production and have begun qualification of a replacement supplier.

While we believe replacement suppliers exist for all components and materials we obtain from single sources, establishing additional or replacement suppliers for any of these components or materials, if required, may not be accomplished quickly. Even if we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we will seek to maintain adequate inventory of the single-source components and materials used in our products in the event of disruption, those inventories may not be sufficient.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on our business.

Manufacturing risks may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

Our business strategy depends on our ability to manufacture and assemble our current and proposed products in sufficient quantities and on a timely basis to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third party suppliers;

- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to build production lines to enable us to efficiently produce products; and
- difficulty identifying and qualifying alternative suppliers for components in a timely manner.

As demand for our products increases, we will need to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and implement manufacturing and quality systems. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, while we expect most new products will utilize the eLab instrument system and existing consumable cartridge, manufacturing of future products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable. Any future interruptions we experience in the manufacturing or shipping of our products could delay our

ability to recognize revenues in a particular quarter and could also adversely affect our relationships with our customers.

Risks Related to Intellectual Property

The extent to which we can protect our business and technologies through intellectual property rights that we own, acquire or license is uncertain.

We employ a variety of proprietary and patented technologies and methods in connection with the assays that we sell or are developing. We license some of these technologies from third parties. We cannot provide any assurance that the intellectual property rights that we own or license provide effective protection from competitive threats or that we would prevail in any litigation in which our intellectual property rights are challenged. In addition, we may not be successful in obtaining new proprietary or patented technologies or methods in the future, whether through acquiring ownership or through licenses from third parties.

Our currently pending or future patent applications may not result in issued patents, and we cannot predict how long it may take for a patent to issue on any of our pending patent applications, assuming a patent does issue.

Other parties may challenge patents issued or exclusively licensed to us, or courts or administrative agencies may hold our patents or the patents we license on an exclusive basis to be invalid or unenforceable. We may not be successful in defending challenges made against our patents and other intellectual property rights. Any third-party challenge to any of our patents could result in the unenforceability or invalidity of some or all of the claims of such patents and could be time consuming and expensive.

The extent to which the patent rights of life sciences companies effectively protect their diagnostic tests and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved.

No consistent policy regarding the proper scope of allowable claims of patents held by life sciences companies has emerged to date in the United States. Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic tests or genomic diagnostic testing. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a "sufficient" additional feature for this purpose is uncertain. Although we do not generally rely on gene sequence patents, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

We cannot predict the breadth of claims that may be allowed or enforced in patents we own or in those to which we have exclusive license rights. For example:

- the inventor(s) named in one or more of our patents or patent applications might not have been the first to have made the relevant invention;
- the inventor (or his assignee) might not have been the first to file a patent application for the claimed invention;
- others may independently develop similar or alternative diagnostic tests and technologies or may successfully replicate our product and technologies;
- it is possible that the patents we own or in which have exclusive license rights may not provide us with any competitive advantages or may be challenged by third parties and found to be invalid or unenforceable;
- any patents we obtain or exclusively license may expire before, or within a limited time period after, the assays and services relating to such patents are commercialized;
- we may not develop or acquire additional proprietary assays and technologies that are patentable; and
- others may acquire patents that could be asserted against us in a manner that could have an adverse effect on our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office, or USPTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, including the first-to-file provisions in particular, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned and licensed patent applications and the enforcement or defense of issued patents that we own or license, all of which could have a material adverse effect on our business and financial condition.

Patent applications in the United States and many foreign jurisdictions are not published until at least eighteen months after filing and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent issues on the application. In addition, publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we were the first to invent the technology (if filed prior to the Leahy-Smith Act) or first to file (if filed after the Leahy-Smith Act). Our competitors may have filed, and may in the future file, patent applications covering technology that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a U.S. patent application covering an invention that is similar to, or the same as, an invention that we own, we may have to participate in an interference or other proceeding in the USPTO or a court to determine priority of invention in the United States, for applications and patents made prior to the enactment of the Leahy-Smith Act. For applications and patents made following the enactment of the Leahy-Smith Act, we may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in our inability to obtain or retain any U.S. patent rights with respect to such invention.

In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag 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 make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Moreover, the USPTO might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, term, enforceability and commercial value of our patent rights are highly uncertain.

The patent prosecution process is expensive and time-consuming, is highly uncertain and involves complex legal and factual questions. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and product candidates. We seek to protect our proprietary position by filing in the United States and in certain foreign jurisdictions patent applications related to our novel technologies and product candidates that are important to our business.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute 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 before it is too late to obtain patent protection. In addition, we may not pursue or obtain patent protection in all major markets. Moreover, in some circumstances, we may not have the right to control the preparation, filing or prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. In some circumstances, our licensors may have the right to enforce the licensed patents without our involvement or consent, or to decide not to enforce or to allow us to enforce the licensed patents. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If any of our licensors fail to maintain such patents, or lose rights to those patents, the rights that we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. In particular, during prosecution of any patent application, the issuance of any patents based on the application may depend upon our ability to generate additional nonclinical or clinical data that support the patentability of our proposed claims. We may not be able to generate sufficient additional data on a timely basis, or at all. Moreover, changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination*inter partes* review, post-grant review or interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights; allow third parties to commercialize our technology or products and compete directly with us, without payment to us; or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned and licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. There are situations in which noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force.

Our intellectual property rights may not be sufficient to protect our competitive position and to prevent others from manufacturing, using or selling competing assays.

The scope of our owned and exclusively licensed intellectual property rights may not be sufficient to prevent others from manufacturing, using or selling competing assays. Competitors could purchase our product and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies and thereby avoid infringing our intellectual property rights. If our intellectual property is not sufficient to effectively prevent our competitors from developing and selling similar diagnostic tests, our competitive position and our business could be adversely affected.

We may become involved in disputes relating to our intellectual property rights, and may need to resort to litigation in order to defend and enforce our intellectual property rights.

Extensive litigation regarding patents and other intellectual property rights has been common in the medical diagnostic testing industry. Litigation may be necessary to assert infringement claims, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. Litigation may even be necessary to resolve disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, USPTO interference or derivation proceedings and related legal and administrative proceedings (*e.g.*, a re-examination) in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time consuming to pursue, and their outcome is uncertain.

Even if we prevail in such a proceeding in which we assert our intellectual property rights against third parties, the remedy we obtain may not be commercially meaningful or adequately compensate us for any damages we may have suffered. If we do not prevail in such a proceeding, our patents could potentially be declared to be invalid, unenforceable or narrowed in scope, or we could otherwise lose valuable intellectual property rights. Similar proceedings involving the intellectual property we exclusively license could also have an impact on our business. Further, if any of our other owned or exclusively licensed patents are declared invalid, unenforceable or narrowed in scope, our competitive position could be adversely affected.

We could face claims that our activities or the manufacture, use or sale of our assays infringe the intellectual property rights of others, which could cause us to pay damages or licensing fees and limit our ability to sell some or all of our assays and services.

Our research, development and commercialization activities may infringe or be claimed to infringe patents or other intellectual property rights owned by other parties of which we may be unaware because the relevant patent applications may have been filed but not yet published. Certain of our competitors and other companies have substantial patent portfolios and may attempt to use patent litigation as a means to obtain a competitive advantage or to extract licensing revenue. In addition to patent infringement claims, we may also be subject to other claims relating to the violation of intellectual property rights, such as claims that we have misappropriated trade secrets or infringed third party trademarks. The risks of being involved in such litigation may also increase as we gain greater visibility as a public company and as we gain commercial acceptance of our diagnostic tests and move into new markets and applications for our assays.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our share price to decline. An adverse determination, or any actions we take or agreements we enter into in order to resolve or avoid disputes, may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be

available from third parties or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our diagnostic tests and offering our services. These outcomes could materially harm our business, financial condition and results of operations.

We may not be able to adequately protect our intellectual property outside of the United States.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices, diagnostic testing and biotechnology, which could make it difficult for us to stop the infringement of our patents and for licensors, if they were to seek to do so, to stop infringement of patents that are licensed to us. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Additionally, prosecuting and maintaining intellectual property (particularly patent) rights are very costly endeavors, and for these and other reasons we may not pursue or obtain patent protection in all major markets. We do not know whether legal and government fees will increase substantially and therefore are unable to predict whether cost may factor into our global intellectual property strategy.

In addition to the risks associated with patent rights, the laws in some foreign jurisdictions may not provide protection for our trade secrets and other intellectual property. If our trade secrets or other intellectual property are misappropriated in foreign jurisdictions, we may be without adequate remedies to address these issues. Additionally, we also rely on confidentiality and assignment of invention agreements to protect our intellectual property in foreign jurisdictions. These agreements may provide for contractual remedies in the event of misappropriation, but we do not know to what extent, if any, these agreements, and any remedies for their breach, will be enforced by a foreign court. If our intellectual property is misappropriated or infringed upon and an adequate remedy is not available, our future prospects will likely diminish. The sale of diagnostic tests that infringe our intellectual property rights, particularly if such diagnostic tests are offered at a lower cost, could negatively impact our ability to achieve commercial success and may materially and adversely harm our business.

Our failure to secure trademark registrations could adversely affect our business and our ability to market our assays and product candidates.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our business and our ability to market our diagnostic tests and product candidates.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information, or the misappropriation of the intellectual property we regard as our own.

We rely on trade secrets to protect our proprietary know how and technological advances, particularly where we do not believe patent protection is appropriate or obtainable. Nevertheless, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, third party contractors, third party collaborators and other advisors to protect our trade secrets and other proprietary information. These agreements generally require that the other party to the agreement keep confidential and not disclose to third parties all confidential information developed by us or made known to the other party by us during the course of the other party's relationship with us. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to seek to pursue a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, courts outside the United States may be less willing to protect trade secrets. In addition, others may independently discover our trade secrets and proprietary information and therefore be free to use such trade secrets and proprietary information. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets and proprietary information may be misappropriated as a result of breaches of our electronic or physical security systems in which case we may have no legal recourse. Failure to obtain, or maintain, trade secret protection could enable competitors to use our proprietary information to develop assays that compete with our assays or cause additional, material adverse effects upon our competitive business position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in our industry, we employ individuals who were previously employed at other companies in our industry or in related industries, including our competitors or potential competitors. We may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the life sciences industry. We cannot guarantee that our product candidates will not infringe third-party patents or other proprietary rights. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including *inter partes* review, interference, or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

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 products. 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. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our own patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees and annuities on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The

USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent 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, our competitors might be able to enter our markets, which could have a material adverse effect on our business.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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 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 an adverse effect on the price of our common stock. Such litigation or proceedings could 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may spend considerable resources developing and maintaining patents, licensing agreements and other intellectual property that may later be abandoned or may otherwise never result in products brought to market.

Not all technologies and candidate products that initially show potential as the basis for future products ultimately meet the rigors of our development process and as a result may be abandoned and/or never otherwise result in products brought to market. In some cases, prior to abandonment we may be required to incur significant costs developing and maintaining intellectual property and/or maintaining license agreements and our business could be harmed by such costs.

We rely on information technology, and if we are unable to protect against service interruptions, data corruption, cyber-based attacks or network security breaches, our operations could be disrupted, and our business could be negatively affected.

We rely on information technology networks and systems to process, transmit and store electronic and financial information; to coordinate our business; and to communicate within our Company and with customers, suppliers, partners and other third parties. These information technology systems may be susceptible to damage, disruptions or shutdowns, hardware or software failures, power outages, computer viruses, cyber-attacks, telecommunication failures, user errors or catastrophic events. If our information technology systems suffer severe damage, disruption or shutdown, and our business continuity plans do not effectively resolve the issues in a timely manner, our operations could be disrupted, and our business could be negatively affected. In addition, cyber-attacks could lead to potential unauthorized access and disclosure of confidential information, and data loss and corruption. There is no assurance that we will not experience these service interruptions or cyber-attacks in the future.

Risks Related to the Company and our Business

We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We received CE-Mark for our eLab instrument and S1 Assay panel in November of 2019 and began commercializing these products in the fourth quarter of 2020. We have also developed products for COVID-19 with the intent to file for FDA EUA. The application for our COVID-19 antibody test was not reviewed by the FDA due to the volume of EUA requests the Agency has received for similar tests. The EUA application for our COVID-19 antigen test was reviewed by the FDA and additional clinical and analytical information was requested. The Company is conducting the additional work and intends to refile the EUA upon completion.

Accordingly, we have a relatively limited operating history upon which to evaluate our business and forecast our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- establish a sales and marketing infrastructure to grow sales of our products and product candidates;
- implement computer based systems for the management of orders, production, inventory, invoicing, and receivable collections;
- increase awareness of our brand;
- manage expanding operations
- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new product candidates;
- respond effectively to competitive pressures and developments;
- enhance our existing product and develop new products;
- obtain and maintain regulatory clearance or approval to commercialize product candidates and enhance our existing products;
- effectively perform clinical trials with respect to our proposed products;
- attract, retain and motivate qualified personnel in various areas of our business: and
- implement and maintain systems and processes that are compliant with applicable regulatory standards.

We may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Sales cycles for our products may be lengthy, which can cause variability and unpredictability in our business.

Some of our products may require lengthy and unpredictable sales cycles, which makes it more difficult to accurately forecast revenues and may cause revenues and operating results to vary from period to period. Our products may involve sales to large public and private institutions which may require many levels of approval and may be dependent on economic or political conditions and the availability of funding from government or public health agencies which can vary from period to period. There can be no assurance that purchases or funding from these agencies will occur or continue. As a result, we may expend considerable resources on unsuccessful sales efforts or we may not be able to complete transactions at all or on a schedule and in an amount consistent with our objectives.

We have limited commercial scale capabilities. If we are unable to successfully implement commercial capabilities and manage our growth, our business will be harmed.

We have been a development stage company and we will need to establish and significantly expand our operations and capabilities. We expect this expansion to occur rapidly and continue to an even greater degree in the future as we continue to commercialize our products, build a sales and marketing organization, and seek marketing clearance from the FDA and international regulatory bodies for our future product candidates. Our growth will place a significant strain on our management, operating and financial systems and our sales, marketing, manufacturing, engineering, product development, and administrative resources. As a result of our growth, operating costs may escalate even faster than planned, and some of our internal systems and processes, including those relating to manufacturing our products, will need to be established and may need to be enhanced, updated or replaced. Additionally, our anticipated growth will increase demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. If we cannot effectively manage our expanding operations, manufacturing capacity and costs, including scaling to meet increased demand and properly managing suppliers, we may not be able to grow or we may grow at a slower pace than expected and our business could be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of medical devices is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. We believe that a significant number of products are currently available, under development, and may become commercially available in the future, for the treatment of indications for which we may try to develop product candidates.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and may also be more successful than us in manufacturing and marketing their products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our technologies and products under development, and our business, may fail if we are not able to successfully commercialize them and ultimately generate significant revenues as a result.

Successful development of technologies and our product candidates will require significant additional investment, including costs associated with additional development, completing trials and obtaining regulatory approval, as well as the ability to manufacture or have others manufacture our products in sufficient quantities at acceptable costs while also preserving product quality. Difficulties often encountered in scaling up production include problems involving production yields, quality control and assurance, shortage of qualified personnel, production costs and process controls. In addition, we are subject to inherent risks associated with new technologies and products. These risks include the possibility that any of our technologies or future products may:

- be found unsafe;
- be ineffective or less effective than anticipated;
- fail to receive necessary regulatory approvals;
- be difficult to competitively price relative to alternative solutions;
- be harmful to consumers or the environment;

- be difficult to manufacture on an economically viable scale;
- be subject to supply chain constraints for raw materials;
- fail to be developed and accepted by the market prior to the successful marketing of alternative products by competitors;
- be difficult to market because of infringement on the proprietary rights of third parties; or
- be too expensive for commercial use.

Furthermore, we may be faced with lengthy market partner or distributor evaluation and approval processes. Consequently, we may incur substantial expenses and devote significant management effort in order to customize products for market partner or distributor acceptance, though there can be no assurance of such acceptance. As a result, we cannot accurately predict the volume or timing of any future sales.

Customers may not adopt our products quickly, or at all.

Customers in the sector in which we operate can be generally cautious in their adoption of new products and technologies. In addition, given the relative novelty of our future planned products, customers of those products may require education regarding their utility and use, which may delay their adoption. There can be no assurance that customers

will adopt our products quickly, or at all.

The significant level of competition in the markets for our products developed in the future may result in pricing pressure, reduced margins or the inability of our future products to achieve market acceptance.

The markets for our future products are intensely competitive and rapidly changing. We may be unable to compete successfully, which may result in price reductions, reduced margins and the inability to achieve market acceptance for our products.

Our competitors may have longer operating histories, significantly greater resources, greater brand recognition and large customer bases than we do. As a result, they may be able to devote greater resources to the manufacture, promotion or sale of their products, receive greater resources and support from market partners and independent distributors, initiate or withstand substantial price competition or more readily take advantage of acquisition or other opportunities.

We may rely on third parties for the production of our future products. If these parties do not produce our products at a satisfactory quality, in a timely manner, in sufficient quantities or at an acceptable cost, our sales and development efforts could be delayed or otherwise negatively affected.

We may rely on third parties for the manufacture of our future products. Our reliance on third parties to manufacture our future products may present significant risks to us, including the following:

- reduced control over delivery schedules, yields and product reliability;
- price increases;
- manufacturing deviations from internal and regulatory specifications;
- the failure of a key manufacturer to perform as we require for technical, market or other reasons;
- difficulties in establishing additional manufacturer relationships if we are presented with the need to transfer our manufacturing process technologies to them;
- misappropriation of our intellectual property; and
- other risks in potentially meeting our product development schedule or satisfying the requirements of our market partners, distributors, direct customers and end users.

If we need to enter into agreements for the manufacturing of our future products, there can be no assurance we will be able to do so on favorable terms, if at all.

If we are unable to establish successful relations with third-party market partners or distributors, or these market partners or distributors do not focus adequate resources on selling our products or are otherwise unsuccessful in selling them, sales of our products may not develop.

We anticipate relying on independent market partners and distributors to distribute and assist us with the marketing and sale of our products. Our future revenue generation and growth will depend in large part on our success in establishing and maintaining this sales and distribution channel. If our market partners and distributors are unable to sell our products, or receive negative feedback from end users, they may not continue to purchase or market our products. In addition, there can be no assurance that our market partners and distributors will focus adequate resources on selling our products to end users or will be successful in selling them. Many of our potential market partners and distributors are in the business of distributing and sometimes manufacturing other, possibly competing, products. As a result, these market partners and distributors may perceive our products as a threat to various product lines currently being distributed or manufactured by them. In addition, these market partners and distributors may earn higher margins by selling competing products or combinations of competing products. If we are unable to establish successful relationships with independent market partners and distributors, we will need to further develop our own sales and distribution capabilities, which would be expensive and time-consuming and might not be successful.

The use of our products may be limited by regulations, and we may be exposed to product liability and remediation claims.

The use of our planned products may be regulated by various local, state, federal and foreign regulators. Even if we are able to comply with all such regulations and obtain all necessary registrations, we cannot provide assurance that our future products will not cause injury to the environment, people, or animals and/or otherwise have unintended adverse consequences, under all circumstances. For example, our products may be improperly combined with other chemicals or, even when properly combined, our products may be blamed for damage caused by those other chemicals. The costs of remediation or products liability could materially adversely affect our results, financial condition and operations.

We may be held liable for, or incur costs to settle, liability and remediation claims if any products we develop, or any products that use or incorporate any of our technologies, cause injury or are found unsuitable during product testing, manufacturing, marketing, sale or use. These risks exist even with respect to products that have received, or may in the future receive, regulatory approval, registration or clearance for commercial use. We cannot guarantee that we will be able to avoid product liability exposure.

At the stage customary to do so, we expect to maintain product liability insurance at levels we believe are sufficient and consistent with industry standards for like companies and products. However, we cannot guarantee that our product liability insurance will be sufficient to help us avoid product liability-related losses. In the future, it is possible that meaningful insurance coverage may not be available on commercially reasonable terms or at all. In addition, a product liability claim could result in liability to us greater than our assets or insurance coverage. Moreover, even if we have adequate insurance coverage, product liability claims or recalls could result in negative publicity or force us to devote significant time and attention to these matters, which could harm our business.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our Company.

We do not expect that internal control over financial accounting and disclosure, even if timely and well established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely affect our business.

Risks Related to this Offering and Our Common Stock

There has been a limited public market for our common stock, and we do not know whether one will develop to provide you adequate liquidity. Furthermore, the trading price for our common stock, should an active trading market develop, may be volatile and could be subject to wide fluctuations in per-share price.

Our common stock is quoted on the Pink Open Market under the trading symbol "BTHE"; historically, however, there has been a limited public market for our common stock. Although we have applied to list our Common Stock on the Nasdaq Stock Market, we cannot assure you that an active trading market for our common stock will develop or be sustained. The liquidity of any market for the shares of our common stock will depend on a number of factors, including:

- the number of stockholders;
- our operating performance and financial condition;
- the market for similar securities;
- the extent of coverage of us by securities or industry analysts; and
- the interest of securities dealers in making a market in the shares of our common stock.

Even if an active trading market develops, the market price for our common stock may be highly volatile and could be subject to wide fluctuations. In addition, the price of shares of our common stock could decline significantly if our future operating results fail to meet or exceed the expectations of market analysts and investors and actual or anticipated variations in our quarterly operating results could negatively affect our share price.

The volatility of the price of our common stock may also be impacted by the risks discussed under this "Risk Factors" section, in addition to other factors, including:

- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- significant sales of our common stock or other securities in the open market;
- variations in interest rates;
- changes in the market valuations of other comparable companies; and
- changes in accounting principles.

Our outstanding warrants and preferred stock may affect the market price and liquidity of the common stock.

As of October 1, 2021, we had approximately 5,300,084 shares of common stock and warrants for the purchase up to approximately an additional 3,450,613 shares of common stock outstanding. We also have outstanding 963,964 shares of our series B preferred stock outstanding, which is convertible into approximately 5.6 million shares of common stock, as well as 1,000,000 shares of our series C preferred stock outstanding, which is convertible into approximately 35 million shares of common stock. As described more fully below, holders of our notes and warrants may elect to receive a substantial number of shares of common stock upon conversion of the notes and/or exercise of the warrants. The amount of common stock reserved for issuance may have an adverse impact on our ability to raise capital and may affect the price and liquidity of our common stock in the public market. In addition, the issuance of these shares of common stock will have a dilutive effect on current stockholders' ownership.

The conversion of outstanding convertible notes into shares of common stock could materially dilute our current stockholders.

As of September 30, 2021, we had approximately $8.4 million aggregate principal amount of convertible notes outstanding, convertible into shares of our common stock at a fixed price of $2.0587 per share. The conversion prices of these notes may be less than the market price of our common stock at the time of conversion, and which may be subject to future adjustment due to certain events, including our issuance of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. If the entire principal amount of all the outstanding convertible notes is converted into shares of common stock, we would be required to issue an aggregate of no less than approximately 4.1million shares of common stock. If we issue all of these shares, the ownership of our current stockholders will be diluted.

Because our common stock may be deemed a low-priced "penny" stock, an investment in our common stock should be considered high-risk and subject to marketability restrictions.

Historically, the trading price of our common stock has been $5.00 per share or lower, and deemed a penny stock, as defined in Rule 3a51-1 under the Exchange Act, and subject to the penny stock rules of the Exchange Act specified in rules 15g-1 through 15g-100. Those rules require broker–dealers, before effecting transactions in any penny stock, to:

- deliver to the customer, and obtain a written receipt for, a disclosure document;
- disclose certain price information about the stock;
- disclose the amount of compensation received by the broker-dealer or any associated person of the broker-dealer;
- send monthly statements to customers with market and price information about the penny stock; and
- in some circumstances, approve the purchaser's account under certain standards and deliver written statements to the customer with information specified in the rules.

Consequently, the penny stock rules may restrict the ability or willingness of broker-dealers to sell the common stock and may affect the ability of holders to sell their common stock in the secondary market and the price at which such holders can sell any such securities. These additional procedures could also limit our ability to raise additional capital in the future.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may also limit a stockholder's ability to buy and sell our common stock, which could depress the price of our common stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require a broker-dealer to have reasonable grounds for believing that the investment is suitable for that customer before recommending an investment to a customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. Thus, the FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares of common stock, have an adverse effect on the market for our shares of common stock, and thereby depress our price per share of common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock may be negatively affected. In the event that we receive securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Certain provisions of our certificate of incorporation and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in stockholders' interest.

Our certificate of incorporation and the Delaware General Corporation Law contain certain provisions that may have the effect of making it more difficult or delaying attempts by others to obtain control of our Company, even when these attempts may be in the best interests of our stockholders. We also are subject to the anti-takeover provisions of the Delaware General Corporation Law, which prohibits us from engaging in a "business combination" with an "interested stockholder" unless the business combination is approved in a prescribed manner and prohibits the voting of shares held by persons acquiring certain numbers of shares without obtaining requisite approval. The statutes and our certificate of incorporation have the effect of making it more difficult to effect a change in control of our Company.

We do not currently or for the foreseeable future intend to pay dividends on our common stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, any return on your investment in our common stock will be limited to the appreciation in the price of our common stock, if any.