UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from to

Commission File Number: 001-34753

GenMark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-2053069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5964 La Place Court **Carlsbad, California**	**92008**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (760) 448-4300

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	GNMK	The NASDAQ Stock Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit). Yes ☒ No ☐

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

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

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

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

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

As of June 30, 2020, the last business day of the registrant’s most recent completed second quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $987,839,000 based on the closing sale price for the registrant’s common stock on the NASDAQ Global Market on that date of $14.71 per share. This number is provided only for the purpose of this report on Form 10-K and does not represent an admission by either the registrant or any such person as to the status of such person.

The number of outstanding shares of the registrant’s common stock on February 22, 2021 was 73,085,716.

GENMARK DIAGNOSTICS, INC.
TABLE OF CONTENTS

Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report"), particularly in Item 1. "Business" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," and the documents incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical fact, are statements that could be deemed to be forward-looking statements, including, but not limited to, statements regarding our future financial position, business strategy, regulatory clearances, research and development efforts, and plans and objectives of management for future operations. When used in this Annual Report, the words "believe," "may," "could," "will," "estimate," "continue," "intend," "expect," "target," "anticipate," "aim," "plan," and similar expressions, including their use in the negative, are intended to identify forward-looking statements.

These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions. They are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. Risks and other factors that may cause such differences include, but are not limited to, those described under the heading "Risk Factors" in Item 1A of Part I of this Annual Report.

In light of these risks, uncertainties, and assumptions, actual results and timing of events could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on such forward-looking statements.

Except as required by law, we do not intend to update these forward-looking statements publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Trademarks and Trade Names

GenMark®, eSensor®, ePlex®, and XT-8® and our other logos and trademarks are the property of GenMark Diagnostics, Inc. or its subsidiaries. All other brand names or trademarks appearing in this Annual Report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress, or products in this Annual Report does not imply that we have a relationship with, or the endorsement or sponsorship of, the trademark or trade dress owners.

Use of External Estimates

This Annual Report includes market share, industry data, and forecasts that we obtained from industry publications and surveys. Industry publications, surveys, and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of such included information. We have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein. While we are not aware of any misstatements regarding the industry and market data presented herein, the data involve risks and uncertainties and are subject to change based on various factors.

PART I.

ITEM 1. BUSINESS

GenMark Diagnostics, Inc. ("GenMark"), is a molecular diagnostics company focused on developing and commercializing multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. References herein to "we," "us," or "our" refer to GenMark Diagnostics, Inc. and its wholly owned subsidiaries, unless the context specifically requires otherwise.

Overview

We currently develop and commercialize high-value instruments and simple to perform, clinically relevant multiplex molecular panels based on our proprietary eSensor electrochemical detection technology. Our eSensor instruments are designed to support a broad range of molecular diagnostic panels with compact, easy-to-use workstations and self-contained, disposable test cartridges.

Our ePlex instrument is a multiplex, sample-to-answer platform that is designed to optimize laboratory efficiency and address a broad range of infectious disease testing needs, including respiratory, bloodstream, and gastrointestinal infections. We are currently commercializing our ePlex instrument and its diagnostic test panels, which we refer to as our ePlex system, in the United States, Europe, and certain other geographic regions. We expect to continue to expand sales of our ePlex system internationally.

In June 2017, we received 510(k) market clearance from the United States Food and Drug Administration ("FDA") for both our ePlex instrument and ePlex Respiratory Pathogen ("RP") Panel. We have also received 510(k) market clearance from the FDA for our ePlex Blood Culture Identification Gram-Positive ("BCID-GP") Panel, Blood Culture Identification Gram-Negative ("BCID-GN") Panel, and Blood Culture Identification Fungal Pathogen ("BCID-FP") Panel. In addition, in response to the COVID-19 outbreak, we received Emergency Use Authorization ("EUA") from the FDA in March 2020 for our ePlex SARS-CoV-2 Test. We also received CE Mark and FDA EUA for our Respiratory Pathogen Panel 2 ("RP2"), which is designed to provide results for SARS-CoV-2 in addition to the other respiratory viruses contained on our ePlex RP Panel. We discontinued the sale of our SARS-CoV-2 Test in the fourth quarter of 2020. We are also developing our ePlex Gastrointestinal Pathogen ("GI") Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

We sell our XT-8 instrument in the United States, along with related diagnostic and research tests, as well as certain custom manufactured reagents, which we collectively refer to as our XT-8 system. Our XT-8 system comprises a compact and easy-to-use workstation and disposable test cartridges that supports a broad range of molecular tests for aiding in the diagnosis of certain infectious diseases and genetic conditions.

Since inception, we have incurred net losses from operations each year, and we expect to continue to incur losses for the foreseeable future. Our net losses for the fiscal years ended December 31, 2020, 2019, and 2018 were approximately $18.6 million, $47.4 million, and $50.5 million, respectively. As of December 31, 2020, we had an accumulated deficit of $532.9 million. Our operations to date have been funded principally through sales of capital stock, borrowings, and cash from operations. We expect to incur increasing expenses over the next several years, principally to further expand our diagnostic test panel menu for our ePlex instrument, as well as to further increase our manufacturing capabilities and commercial organization.

Our Strategy

Our goal is to become the market leading provider of automated, multiplex molecular diagnostic testing systems. In order to achieve this objective, we intend to:

- ***Drive Commercialization of our ePlex System***. We believe our ePlex system is an attractive solution for a broad range of hospitals and laboratories that need rapid, actionable identification of infectious pathogens as well as those hospitals and laboratories that may lack the technical or economic resources to perform molecular diagnostic testing with existing products and technology. We believe the ePlex system will expand our current potential user base from approximately 1,000 domestic customers to approximately 12,000 potential customers globally.
- ***Expand our Menu of Clinical Diagnostic Products.*** We intend to develop a broad menu of molecular diagnostic tests for our ePlex instrument that we believe will satisfy important medical needs and present attractive commercial opportunities. We are developing our ePlex GI Panel for the detection of pathogens associated with gastrointestinal infections. In addition, we are actively evaluating the development of additional panels that we believe will meet important, unmet clinical needs.
- ***Grow our Installed Base of Customers***. We have identified laboratories and hospitals that we believe will benefit from our product portfolio. We intend to leverage our commercial organization and our international distribution network to drive placements of our instruments. We anticipate that the expansion of our installed base of customers will drive sales of our test panel cartridges, from which we expect to generate the majority of our revenues for the foreseeable future.

- ***Increase Test Utilization***. We intend to increase the use of our diagnostic tests by developing and offering tools and support tailored to our products, such as education programs and seminars, product training for our customers, and advanced software features. Additionally, we plan to invest in research studies that establish the clinical, health, and economic utility of multiplex molecular diagnostic panels, which we believe will increase the adoption of our products.
- ***Develop Partnerships with Relevant Third Parties***. We plan to establish partnerships with other stakeholders in the diagnostic industry to expand our commercial, operations, and research and development capabilities. We anticipate that these partnerships will increase awareness of our ePlex system as well as bring additional value to our customers, helping us secure and grow our business.
- ***Support Our Existing XT-8 Business***. We currently offer our XT-8 instrument in the U.S. market and sell numerous diagnostic and research panels and custom manufactured reagents for use on our XT-8 system. We expect our XT-8 system to remain an important piece of our overall business for the foreseeable future and we intend to continue supporting this product line in the field with application support, customer education, and training.

Our Technology

Our eSensor Technology

Our proprietary eSensor technology is based on the principles of deoxyribonucleic acid ("DNA") hybridization and electrochemical detection. DNA naturally forms a double-stranded structure, with each strand binding with high affinity, or hybridizing, only to a complementary strand. Our technology takes advantage of this highly specific binding by first creating two types of single-stranded DNA, the capture probe and the signal probe. The capture probe and signal probe are each complementary to a different segment of the target DNA that is the focus of the particular diagnostic test. Using our technology and processes, we attach our capture probes to a proprietary monolayer on the surface of a gold electrode within our test cartridges. We separately attach ferrocene labels to our signal probes.

Before placing the sample into our XT-8 test cartridge, the technician mixes the amplified DNA sample with our signal probe. If the target biomarker is present in the prepared patient sample, a segment of the biomarker DNA will hybridize with a solution containing our signal probe. This solution is then run past an electrode, against which our capture probes have been immobilized. The as-yet unbound segment of the target biomarker binds to our capture probe, creating a target DNA, signal probe, capture probe complex at the surface of the electrode. This complex produces an electrochemical signal which is analyzed and interpreted by our XT-8 system.

With our ePlex sample-to-answer test cartridges, the operator adds a patient sample directly or with minimal preparation into the sample chamber, closes the lid, and inserts the test cartridge into the ePlex instrument. Within the instrument, the same steps performed by a technician with the XT-8 system are performed within the ePlex test cartridge, resulting in the delivery of target DNA and signal probes to the eSensor electrodes within the ePlex cartridge. As with XT-8, when a complex forms as a result of a target match, the complex produces an electrochemical signal that is interpreted by the ePlex system.

Our XT-8 and ePlex test panel cartridges utilize the combination of distinct electrodes and multiple signal probes to detect dozens of target biomarkers from a single sample, thereby enabling highly multiplexed testing. Our eSensor technology is highly specific for the target biomarker, and is not based on optical or fluorescent detection. As a result, our diagnostic tests are less prone to sample contamination risk and do not require many of the time-consuming washing and preparation steps required by competing technologies. The sample preparation steps required before using our XT-8 test cartridges are nucleic acid purification and polymerase chain reaction ("PCR") amplification, which involves amplifying, or generating billions of copies of the target DNA molecules, followed by transfer of the sample to our test cartridge and insertion of the test cartridge into any open module in our XT-8 system. In some XT-8 tests, amplified DNA is subject to an additional enzymatic treatment to produce a single-stranded-DNA. In contrast, the ePlex system generally requires no pre-analytic steps to be performed by the user, except, in limited cases, certain minimal up-front sample handling.

We believe our proprietary electrochemical detection technology has several advantages over other signal detection platforms, including high sensitivity and accuracy, streamlined sample preparation, efficient multiplexing, effective use of lab space, low maintenance, and the ability to cost-effectively develop additional tests.

Digital Microfluidics

Digital microfluidics is another innovative technology included within our ePlex system which we have exclusively licensed within a defined field of use from an affiliate of Illumina, Inc. Digital microfluidics is a technique for moving small droplets of liquid using electrowetting, a process for making a surface hydrophobic or hydrophilic based on the application of a voltage to a surface. Our ePlex printed circuit board contains eSensor electrodes capable of nucleic acid detection along with electrowetting electrodes capable of digital microfluidics. The ePlex system uses numerous choreographed digital inputs to perform the fluid manipulations associated with sample-to-answer molecular diagnostics. Drops are dispensed, mixed, merged, heated, cooled, split and delivered, all under

precise and programmable digital control. In this manner, standard procedures of the molecular diagnostics lab (e.g., DNA purification, PCR, exonuclease digestion, etc.) can be performed automatically within our ePlex cartridge.

Our Instrument Systems

Our ePlex Instrument. Our ePlex instrument is a multiplex, sample-to-answer platform that fully integrates nucleic acid extraction, amplification, and detection and has a modular design consisting of an integrated touch screen and up to four analyzers. Each analyzer contains six test cartridge modules into which individual ePlex panel test cartridges are placed. The test cartridge modules operate independently supporting continuous random access of up to 24 independent test cartridges. We also offer a near-patient configuration of our ePlex instrument for lower volume customers, which contains three independent test cartridge modules in a single analyzer. The ePlex instrument software is designed to integrate into the hospital network and communicate with Laboratory Information Systems ("LIS") bi-directionally using multiple file formats. As part of its networking capability, ePlex is also capable of providing remote access support, which allows our customer technical support personnel remote access to the ePlex system to troubleshoot and run system checks remotely. The ePlex system also incorporates a series of software features for epidemiology tracking, external control tracking, and the ability to add target-specific comments for each result, which may include local practice or antimicrobial stewardship guidelines. In June 2017, we received 510(k) market clearance from the FDA for both our ePlex instrument and ePlex RP Panel. We have also received 510(k) market clearance from the FDA for our ePlex BCID-GP, BCID-FP, and BCID-GN Panels. In addition, in response to the COVID-19 outbreak, we received EUA from the FDA in March 2020 for our ePlex SARS-CoV-2 Test. We also received CE Mark and FDA EUA for our RP2 Panel, which is designed to provide results for SARS-CoV-2 in addition to the other respiratory viruses contained on our ePlex RP Panel. We are also developing our ePlex GI Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

Our XT-8 Instrument. Our XT-8 instrument is a post-PCR multiplex workstation that has a modular design consisting of an integrated touch screen and up to three analyzers. Each analyzer contains eight modules into which individual test panel cartridges are placed. The test cartridge modules operate independently of each other allowing up to 24 independent test panel cartridges to be loaded at one time, with the remaining modules available for use at any future time while the system is running. We offer the following four FDA-cleared panels on our XT-8 instrument: a Respiratory Viral Panel, a Cystic Fibrosis Genotyping Test, a Thrombophilia Risk Test, and a Warfarin Sensitivity Test. We also offer a Hepatitis C ("HCV") Genotyping Test and associated custom manufactured reagents, as well as a 2C19 Genotyping Test, each of which is available for use with the XT-8 instrument for research use only ("RUO").

Market Opportunity

We believe the aggregate global total addressable market for the tests we currently offer, are actively developing on ePlex, or may consider developing is approximately $3.3 billion. Many factors are driving the strong opportunity in this market, including increased demand for infectious disease diagnostic solutions and an increased focus on value-based medical care that enhances patient outcomes, improves key quality metrics, and reduces the total cost-of-care.

Research and Development

Our research and development ("R&D") team is focused on expanding our ePlex test menu. In addition, our R&D team is supporting the following initiatives:

- ***On Market Product Support.*** A role of our R&D team is to assist our manufacturing and quality assurance teams in ensuring high product quality and thorough complaint handling and investigation. This team also supports improvements in quality control methods and metrics and is an active participant in the continuous improvement processes utilized by our product manufacturing teams.
- ***Improving the Clinical and Practical Utility of our Tests.*** Our R&D organization also supports the clinical utility and value of our molecular diagnostic test panels. We have previously and intend to continue to partner with academic and reference laboratories to perform validation and clinical studies on our tests. Key aspects of our efforts are aimed at improving workflow in the laboratory setting, positively comparing our test panels to historical or "gold standard" tests, and demonstrating that our test panels can help improve patient care and lower diagnostic and medical treatment costs. We intend to publish the results from these clinical studies in peer-reviewed or trade journals, submit them to regulatory bodies, and present them at industry conferences in support of our commercialization strategy.

Manufacturing

We manufacture our proprietary test panel cartridges, certain related components, and ancillary reagents in our Carlsbad, California facilities. We perform reagent formulation, test cartridge manufacturing, and packaging of final components and test cartridges in accordance with applicable guidelines for medical device manufacturing. We currently lease an aggregate of approximately 160,000 square feet at three nearby locations in Carlsbad, California, where we maintain our corporate office and manufacturing facilities.

We outsource the manufacture of our ePlex instrument to Plexus Corp. ("Plexus"). We currently maintain an inventory of XT-8 instruments and related components to satisfy the expected demand for our XT-8 system for the foreseeable future, as well as to service XT-8 instruments installed at customer locations. We rely on third party suppliers, including in certain instances, sole source suppliers, for certain raw materials and other supplies and components used in our products.

We have implemented a quality management system designed to comply with FDA regulations and ISO standards governing diagnostic medical device products. These regulations control the design, manufacture, testing, and release of diagnostics products, as well as raw material receipt and control. In 2012, our Carlsbad, California corporate headquarters facility obtained ISO 13485 certification. We control methods for the consistent manufacturing of our proprietary test panel cartridges and reagents at our facilities. Our key outsourcing partners are regularly audited to help ensure a continual supply of high quality components.

We plan to continue to manufacture components that we determine are highly proprietary or highly customized, while outsourcing more commodity-like components. We are likely to establish additional outsourcing partnerships as we manufacture additional products.

Sales and Marketing

Our current sales and marketing strategy is to expand our business globally with the commercialization of our ePlex system in the United States, Europe, and certain other geographic regions, while also continuing to support the placement and use of our XT-8 system in the United States. Our products are sold in the United States through a geographically dispersed direct sales and technically specialized service organization, which is supported by a centralized team of product managers and marketing, customer support, and technical support personnel. We primarily utilize third party distributors to sell our ePlex system internationally, which are augmented by a limited set of direct sales and technical support personnel.

Our sales representatives typically have experience in molecular diagnostics and a network of laboratory contacts within their respective territories. We utilize our representatives' knowledge along with market research databases to target and qualify our customers. We execute a variety of sales campaigns and strategies to meet the buying criteria of the different customer segments we serve. To support the growth in our customer base, we continue to make investments in these customer facing organizations.

Our sales cycle typically includes customer evaluations and validations of our products. Upon successful validation, a customer will generally acquire our instrument in one of the following ways:

- ***Reagent Rental:*** A reagent rental agreement generally provides that a customer commits to purchase a minimum number of test cartridges over the term of the agreement, and a portion of the charge for each cartridge is attributable to a usage fee for the instrument.
- ***Capital Purchase:*** The instrument is paid for upfront and in its entirety by the customer. Customers are also eligible to receive structured pricing incentives if they enter into an optional annual minimum cartridge purchase commitment.

Customers

Our target customers include hospital-based and reference laboratories, as well as research institutions. We believe our ePlex system will expand our current potential user base from approximately 1,000 domestic customers to approximately 12,000 potential customers globally. In 2020, 2019, and 2018, sales to one customer represented 10%, 14%, and 16%, respectively, of our total revenue.

Competition

We primarily face competition in the molecular diagnostic testing markets with testing products and systems developed by public and private companies such as bioMerieux (which acquired Biofire Diagnostics, Inc.), Luminex Corporation (which acquired Nanosphere, Inc.), Danaher Corporation (which acquired Cepheid), Qiagen (which acquired Stat-Dx), Siemens (which acquired Fast Track Diagnostics), T2 BioSystems, Accelerate Diagnostics, Hologic, Inc., Seegene, Mobidiag, Qvella, Curetis, Bosch/Randox, aprimeo diagnostics, Roche Diagnostics, and Abbott Molecular Diagnostics. Our diagnostic tests also face competition with laboratory developed tests ("LDTs") developed by national and regional reference laboratories and hospitals. We believe that our testing systems

compete largely on the basis of accuracy, reliability, enhanced laboratory workflow, multiplex capability, ease-of-use, turnaround time, customer service and support, patient safety, and return on investment for customers.

Many of our competitors have substantially greater financial, technical, research, and other resources and larger, more established marketing, sales, and distribution organizations than we do. Many of our competitors also offer broader product lines and have greater brand recognition than we do. Moreover, our existing and new competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue.

Intellectual Property

To establish and protect our proprietary technologies and products, we rely on a combination of our patents, copyrights, trademarks, and trade secrets, as well as other intellectual property rights in our technology and business information. Our intellectual property portfolio for our core electrochemical technology was initially built through the combination of our acquisition of the Clinical Micro Sensors business from Motorola and licensing patents from the California Institute of Technology. We also have exclusively licensed the digital microfluidics technology utilized in our ePlex system within a defined field of use from an affiliate of Illumina.

We believe that our patent portfolio, which includes over 100 owned and licensed U.S. and foreign patents and approximately 25 pending applications, and other intellectual property rights provide us with extensive protection of our eSensor systems. We continue to pursue the issuance of new patents to protect our ongoing research, development, and commercial activities, in particular with respect to our ePlex system and related consumables. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. Several of our pending applications have the potential to mature into patents that may expire between 2029 and 2039. Our success depends to a significant degree upon our ability to police infringement and continue to develop proprietary products and technologies without infringing the intellectual property rights of others.

We also rely in part on trade secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees, and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in intellectual property, such as patents and copyrights arising from their work for us. All employees sign an agreement not to compete unfairly with us during their employment and upon termination of their employment through the misuse of confidential information.

We also have filed for registration, or obtained registration, in the U.S. and other countries for marks used with our products and technology. Our issued trademarks in the United States and/or Europe include GenMark®, GenMark DX®, eSensor®, ePlex®, and XT-8®, among others.

Government Regulation

The design, development, manufacture, testing and sale of our molecular diagnostic products are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and foreign regulatory agencies.

Regulation by the FDA

In the United States, the Federal Food, Drug, and Cosmetic Act (“FDCA”), FDA regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. The FDA regulates the design, manufacturing, servicing, sale, and distribution of medical devices, including molecular diagnostic test panels and instrumentation systems. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution.

The two primary types of FDA marketing authorization required applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA. We have obtained 510(k) market clearance from the FDA for the following molecular diagnostic tests for use on our XT-8 system: the Respiratory Viral Panel, the eSensor Warfarin Sensitivity Test, the Cystic Fibrosis Genotyping Test, and the Thrombophilia Risk Test. We have also obtained 510(k) market clearance from the FDA for our ePlex instrument, as well as our ePlex RP, BCID-GP, BCID-GN, and BCID-FP Panels. In addition, in response to the COVID-19 pandemic, the FDA has granted EUA for certain diagnostic tests and panels that are designed to detect SARS CoV-2. We received EUA from the FDA in March 2020 for our ePlex SARS-CoV-2 Test. We also received FDA EUA for our ePlex RP2 Panel which is designed to provide results for SARS-CoV-2 in addition to the other respiratory viruses contained on our ePlex RP Panel. We discontinued the sale of our SARS-CoV-2 Test in the fourth quarter of 2020.

Proposed Regulation of LDTs. In October 2014, the FDA promulgated draft guidance which describes a new proposed regulatory framework for LDTs. Based on this proposal, clinical laboratories that develop and use LDTs would be required to comply

with specific regulatory requirements (e.g., adverse event reporting, quality system regulation ("QSR"), premarket submission, and FDA review) prior to the use of LDTs for clinical diagnostic purposes.

Regulation after FDA Clearance or Approval. Any devices we manufacture or distribute pursuant to clearance or approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. We are required to adhere to applicable regulations setting forth detailed Good Manufacturing Practices ("GMP") as set forth in the QSR, which includes testing, control, and documentation requirements. Non-compliance with these standards can result in fines, injunctions, civil penalties, recalls, or seizures of products, total or partial suspension of production, refusal of the government to grant 510(k) clearance or PMA of devices, withdrawal of marketing approvals, and criminal prosecutions. We have designed and implemented quality system processes within our manufacturing facilities in order to comply with the FDA's GMP requirements.

Because we are a medical device manufacturer, we must also comply with the FDA's medical device reporting requirements whenever there is evidence that reasonably suggests that one of our products may have caused or contributed to a death or serious injury. We must also report any incident in which our product has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur.

Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Medical devices approved or cleared by the FDA may not be promoted for unapproved or uncleared uses, otherwise known as "off-label" promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution. We have implemented quality system processes and advertising/promotional policies designed to comply with these requirements.

Environmental Regulations. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. Some of these laws require us to obtain licenses or permits to conduct our operations. We have numerous policies and quality system procedures in place to ensure compliance with these laws and to minimize the risk of occupational exposure to hazardous materials. We do not expect the operations of our products to produce significant quantities of hazardous or toxic waste or radiation that would require the use of extraordinary disposal practices. Although the costs to comply with these applicable laws and regulations have not been material, we cannot predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Export of Our Products. Medical devices that are legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval. Devices that have not been approved or cleared in the U.S. must follow the export provisions of the FDCA. Depending on which section of the FDCA we may export under, we may need to request an export permit letter or export certificate, or we may need to submit a simple notification. Export certificates may be requested by foreign customers or foreign governments to provide proof of the products' status as regulated by the FDA. The export certificate is prepared by the FDA and contains information about a product's regulatory or marketing status in the United States.

Clinical Laboratory Improvement Amendments of 1988. The use of our products is also affected by the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and related federal and state regulations, which provide for regulation of laboratory testing. Any customers using our products for clinical use in the United States will be regulated under CLIA, which establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. In particular, these regulations mandate that clinical laboratories must be certified by the federal government or a federally approved accreditation agency, or must be located in a state that has been deemed exempt from CLIA requirements because the state has in effect laws that provide for requirements equal to or more stringent than CLIA requirements. Moreover, these laboratories must meet quality assurance, quality control, and personnel standards, and they must undergo proficiency testing and inspections. The CLIA standards applicable to clinical laboratories are based on the complexity of the method of testing performed by the laboratory, which range from "waived" to "moderate complexity" to "high complexity." Our molecular diagnostic tests for use on our XT-8 system are categorized as "high complexity" and our ePlex instrument and ePlex RP, BCID-GP, BCID-GN, and BCID-FP Panels are categorized as "moderate complexity."

Foreign Government Regulation. We intend to market our products in European and other international markets. The regulatory pre-market requirements for *in vitro* diagnostic ("IVD") devices vary from country to country. Some countries impose product standards, packaging requirements, labeling requirements, and import restrictions on devices. Each country has its own tariff regulations, duties, and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject us to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Fraud and Abuse Regulations

We are subject to numerous federal and state health care anti-fraud laws, including the federal anti-kickback statute and False Claims Act ("FCA"), that are intended to reduce waste, fraud, and abuse in the health care industry. These laws are broad and subject to evolving interpretations. They prohibit many arrangements and practices that are lawful in industries other than health care,

including certain payments for consulting and other personal services, some discounting arrangements, the provision of gifts and business courtesies, the furnishing of free supplies and services, and waivers of payments. In addition, many states have enacted or are considering laws that limit arrangements between medical device manufacturers, physicians, and other health care providers and require significant public disclosure concerning permitted arrangements. These laws are vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. We must operate our business within the requirements of these laws and, if we were accused of violating them, we could be forced to expend significant resources on investigation, remediation, and monetary penalties.

Patient Protection and Affordable Care Act

Our operations are affected by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the Health Care Act. The Health Care Act requires manufacturers to report to the Department of Health and Human Services detailed information about financial arrangements with physicians and teaching hospitals. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. Failure to comply with these requirements subjects the manufacturer to significant civil monetary penalties.

Employees and Human Capital

The COVID-19 pandemic continues to impact lives and businesses around the world. We have taken proactive steps to help protect the health and safety of our employees and maintain business continuity. A significant number of our office workers continue to telecommute. Within our production and office areas we have also established a number of safety protocols, including face covering and physical distance requirements, enhanced cleaning, and temperature screening stations, among other measures. We have also established a COVID-19 response team, which, among other activities, has developed a robust contact tracing program to identify employees who were in close contact with any ill employees in the workplace.

As of December 31, 2020, we had 618 employees, of which 413 were involved in operations, manufacturing, and quality assurance; 99 employees were involved in research and development; 62 were involved in sales and marketing; and 44 were involved in general and administrative functions. Our success will depend in large part upon our ability to attract and retain employees. The members of our management team and our board of directors come from diverse backgrounds, and we seek to attract and recruit diverse, talented, experienced and motivated employees. We monitor our progress with human capital metrics such as turnover, time to fill open roles, and rate of internally developed talent. We face competition in this regard from other companies, research and academic institutions, government entities, and other organizations. Our market position, reputation, and culture support our ability to recruit and retain talented employees across our departments. None of our employees are covered by a collective bargaining agreement.

Business Seasonality

We have historically experienced higher net sales in the first and fourth quarters of the year compared to the second and third quarters of the year due in part to the typical seasonality of influenza outbreaks in the Northern hemisphere. However, historical seasonal patterns should not be considered reliable indicators of our future net sales or financial performance.

Corporate and Available Information

Our corporate office is located at 5964 La Place Court, Carlsbad, California. We also lease additional manufacturing space near our corporate office in Carlsbad, California.

We make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (“SEC”). We also make these documents and certain public financial information available on our website, which is www.genmarkdx.com. Our SEC reports and other financial information can be accessed through the investor relations section of our website. Some of the information found on our website is not part of this or any other report we file with or furnish to the SEC.

ITEM 1A. RISK FACTORS

You should consider each of the following factors as well as the other information in this Annual Report in evaluating our business and our prospects. The risks and uncertainties described below are not the only ones we face. If any of the following risks actually occur, our business and financial results could be harmed. In that case, the trading price of our common stock could decline. You should also refer to the other information set forth in this Annual Report, including our financial statements and the related notes.

Risks Related to the COVID-19 Pandemic

Our business is subject to risks associated with widespread public health crises, including the current COVID-19 pandemic.

Our business could be adversely affected by the widespread outbreak of a contagious disease, such as the recent outbreak of respiratory illness caused by the novel coronavirus ("COVID-19"). In March 2020, we received Emergency Use Authorization ("EUA") from the FDA for our ePlex SARS-CoV-2 Test. We have also experienced a recent increase in demand for our respiratory products, including our ePlex Respiratory Pathogen ("RP") Panel, due to the COVID-19 pandemic. In addition, we were recently awarded up to $749,000 from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Department of Health and Human Services ("HHS") Office of the Assistant Secretary for Preparedness and Response ("ASPR"), to develop and pursue an EUA of a diagnostic panel ("RP2") that incorporates the novel SARS-CoV-2 viral target into our existing ePlex RP Panel. In October 2020, we received EUA for our RP2 Panel from the FDA and transitioned our customers from the ePlex SARS-COV-2 Test to RP2. If the FDA were to revoke the EUA for our RP2 Panel, or if the FDA determines that an EUA is no longer an appropriate regulatory pathway for our RP2 Panel, it may be more complex, time-consuming, and costly to obtain regulatory approval for such products and our business results and financial performance may be adversely affected.

We are monitoring the global pandemic of COVID-19 and have implemented mitigation measures for potential risks to our employees. It is critical that we keep our employees safe and informed in order to maintain our ongoing business operations and employee safety. We have taken precautions related to employee screening, social distancing, and facility hygiene, as well as imposed certain travel limitations on our employees and encouraged our employees to work remotely, if possible. Nevertheless, an outbreak of COVID-19 or any other contagious disease among our critical employee population, or travel restrictions or other actions imposed by governmental authorities as a result of the pandemic, could materially and adversely disrupt our ability to manufacture and distribute our products, develop additional products, and/or service and support our customers.

We are also evaluating the potential impacts of the current pandemic on our global supply chain and are working closely with our suppliers and governmental authorities to ensure continued access to key raw materials, supplies, and personal protective equipment needed to manufacture our products. This is a rapidly evolving situation, and we will continue to monitor developments affecting our customers, employees and suppliers and take additional precautions we believe are warranted. The extent of the impact of COVID-19 on our business, financial condition, and results of operations remains uncertain.

If our essential employees who are unable to telework, or become ill or otherwise incapacitated, our operations may be adversely impacted.

Consistent with rapidly changing federal, state and local governmental orders and recommendations, we have implemented telework policies wherever possible for appropriate categories of our employees. Employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering, temperature checking, and increased sanitation standards in an attempt to maintain the health and safety of our workforce. We are following guidance from the Center for Disease Control ("CDC") and the Occupational Safety and Health Administration (OSHA) regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and wellbeing of our employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may not otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

Operational and General Business Risks

We may not successfully commercialize our ePlex system at the levels we anticipate.

Our current plan for achieving positive cash flow and our future growth projections relies upon the successful commercialization of our ePlex system at the levels we project. Our ePlex system integrates automated nucleic acid extraction and amplification with our eSensor technology to allow operators to place raw or minimally prepared patient samples directly into our test cartridges and obtain clinically relevant results. We believe that our ePlex system offers certain advantages over competitive systems, including superior

multiplexing capability, reduced hands-on processing time, and testing capacity and flexibility, among other attributes. However, the commercial success of ePlex will depend on a number of factors, including, but not limited to:

- Our ability to consistently manufacture highly complex products that deliver valid and accurate results at the level required for large-scale market adoption;
- product reliability;
- overall market acceptance;
- our ability to offer a broad and clinically relevant test menu at a competitive price;
- our ability to overcome technical limitations in connection with the development of new products;
- our ability to effectively sell our products into integrated delivery networks and group purchasing organizations;
- adequate reimbursement for our products; and
- the development of clinical utility and health economic evidence to support adoption of our products.

If we are unsuccessful in effectively commercializing our ePlex system at the levels we project within our expected time frame, or at all, our investment in anticipation of growth that does not materialize, or which develops more slowly than we expect, may harm our financial results, reduce our cash balances, and result in overcapacity, which may adversely affect our business and future prospects.

From time to time we and our key suppliers experience, and may in the future experience, difficulties scaling manufacturing operations to the levels required to support our anticipated growth in a timely and cost effective manner.

To date, we have produced our products in limited quantities relative to the quantities necessary to achieve our desired revenue growth. In addition, we have experienced a significant increase in demand for our ePlex RP Panel, ePlex SARS-CoV-2 Test (sales of which we discontinued in the fourth quarter of 2020), and our ePlex RP2 Panel as a result of the current COVID-19 pandemic. Developing the necessary manufacturing and quality procedures internally and in conjunction with our key suppliers for a significant number of our newly developed, highly complex products and product components is a challenging process. From time to time we and our suppliers experience, and may in the future experience, manufacturing variability and may not be able to consistently produce sufficient quantities of high quality products and product components at the levels necessary to achieve our revenue growth expectations or to support customer demand or our product development timelines. We recently leased a new 73,000 square foot facility, which we are currently in the process of building out to significantly increase our production capacity. Nevertheless, if we or our key suppliers encounter difficulties in producing sufficient yields of high quality products or product components, or scaling manufacturing operations as a result of, among other things, process and manufacturing transfer complexities, quality control and quality assurance issues, rapid increases in demand, and/or availability or the quality of subcomponents, equipment, and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results or product development goals within the time frame we expect, or at all. In addition, we may encounter difficulties managing our supply chain and ensuring timely delivery of sufficient quantities of our products. If we are unable to manage such difficulties, we may be unable to meet our product supply commitments and/or customer expectations, which would adversely impact our financial results and our reputation may suffer and could subject us to potential financial liability.

Finding solutions to product quality, reliability, variability, and raw material sourcing issues is time consuming and expensive, and we may incur significant additional costs or lose revenue as a result of, among other things, delayed product introduction, product recalls, shipment holds, scrapped material, manufacturing delays, scale-up challenges, or inefficiencies, and warranty and service obligations. In addition, we are implementing a number of measures to reduce the cost of manufacturing our ePlex products. If these efforts are unsuccessful, or if these efforts prove less successful than we anticipate or do not deliver the results within the timeframes we expect, we may not achieve our profitability targets in a timely manner, or at all.

To manage our anticipated future growth effectively, we must enhance our manufacturing and supply chain capabilities, infrastructure and manufacturing operations, information technology infrastructure, and financial and accounting systems and controls. Organizational growth and scale-up of operations could strain our existing managerial, operational, financial, and other resources. If our management is unable to effectively prepare for our expected future growth, our expenses may increase more than anticipated, our revenue could grow more slowly than expected, and we may not be able to achieve our commercialization, profitability, or product development goals. Our failure to effectively implement the necessary processes and procedures and otherwise prepare for our anticipated growth could have a material adverse effect on our future financial condition and prospects.

Disruptions in the supply of raw materials, consumable goods, or other key product components, or issues associated with their cost or quality from our single source suppliers, could result in delays or difficulties successfully commercializing our ePlex system or a significant disruption in sales and profitability.

We must manufacture or engage third parties to manufacture components of our products in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs and complying with regulatory requirements. Our

instrument systems and certain critical components are custom-made by only a few outside suppliers. In certain instances, we and our suppliers have a sole source supply for certain key products, product components, ancillary items, and raw materials used to run our tests. If we are unable to satisfy our forecasted demand from existing suppliers for our products, or we or our suppliers are unable to find alternative suppliers for key product components, ancillary items or raw materials at reasonably comparable prices, it could have a material adverse effect on our financial condition and results of operations. Additionally, although we have entered into supply agreements with most of our suppliers of strategic reagents and parts to help ensure component availability and flexible purchasing terms with respect to the purchase of such components, if our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable, cost-effective alternative on reasonable terms, or at all, which could limit our ability to manufacture our products.

In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on seasonality, inventory levels, current market trends, product development timelines, overall capacity, and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our products, there could be significant differences between our estimates and the actual amounts of products we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

Reliance on third-party manufacturers entails risk to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;
- the potential obsolescence and/or inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
- the inability to qualify alternate sources without impacting performance claims of our products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers;
- the imposition of tariffs on certain product components based on our suppliers' location;
- the potential for financial hardship or other detrimental circumstances at key suppliers that may impact our ability to source key materials or services required for the manufacturing of our products; and
- increases in prices of raw materials and key components.

The manufacturing operations for our test panel cartridges use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly and time consuming to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facilities or the facilities of any of our key suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, global health pandemics or otherwise, would limit our ability to meet customer demand for our products and would have a material adverse effect on our business, financial condition, and results of operations. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

Our financial results will depend on the acceptance and increased demand among our target customers and the medical community of our molecular diagnostic technologies and products.

Our future success depends on the belief by our target customers and the medical community that our molecular diagnostic products, including our ePlex instrument and its panel test menu, are a reliable, medically-relevant, accurate and cost-effective replacement for other diagnostic testing methods. Our business success depends on our ability to convince our target customers to perform these tests internally with our products if they have historically outsourced their testing needs or have historically used non-molecular methods to perform such testing, or to replace their current molecular testing platforms with our system and its related test panel offerings.

Many other factors may affect the market acceptance and commercial success of our molecular diagnostic technology and products, including:

- the relative convenience, ease of use, accuracy, reliability, validity, scalability, cost, and time-to-result of our diagnostic products over competing products;

- the introduction of new technologies and competing products that may make our technologies and products a less attractive solution for our target customers;
- the breadth and relevance of our menu of available diagnostic test panels relative to our competitors;
- our success in training our customers in the proper use of our products;
- the acceptance in the medical community and key opinion leaders of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

Professional societies, government agencies, practice management groups, private health/science foundations and organizations involved in healthcare issues may publish guidelines, recommendations, or studies for the healthcare and patient communities. Recommendations of government agencies or these other organizations may relate to such matters as cost-effectiveness and use of related products. Organizations like these have in the past made recommendations about our competitors' products, such as the need for less frequent screening tests, which could result in reduced product sales. Moreover, the perception by the investment community or stockholders that recommendations, guidelines, or studies will result in decreased use of our products could adversely affect the prevailing market price for our common stock.

We face intense competition from established and new companies in the molecular diagnostics field and expect to face increased competition in the future.

The markets for our technologies and products are highly competitive and we expect the competitive intensity to increase. We compete with companies engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Categories of our competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, including: Luminex (which acquired Nanosphere, Inc.); bioMerieux (which acquired BioFire Diagnostics, Inc.); Abbott Molecular Diagnostics; Qiagen NV (which acquired Stat-Dx); Siemens (which acquired Fast Track Diagnostics); T2 BioSystems; Accelerate Diagnostics; Hologic, Inc.; Seegene; and Danaher Corporation (which acquired Cepheid);
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods, including Quest Diagnostics Incorporated and Laboratory Corporation of America; and
- companies that manufacture laboratory-based tests and analyzers, including: Danaher; Siemens; Hologic, Inc.; Qiagen; bioMérieux; Roche Diagnostics; and Abbott Molecular Diagnostics.

Our diagnostic test panels also face competition from LDTs developed by national and regional reference laboratories and hospitals. LDTs may not currently be subject to the same regulatory requirements, including those requiring clinical studies and FDA review and clearance or approval that may apply to our diagnostic products. In addition, our RP2 Panel will face significant competition by numerous companies that have received or are expected to receive EUA from the FDA for tests or multiplex panels that are designed to detect the virus which leads to COVID-19.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies, our competitors improve their current products and expand their menu of diagnostic tests, and as we expand our operations internationally. Many of our current and potential competitors have greater name recognition, more substantial intellectual property portfolios, longer operating histories, additional test menu, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, and more extensive manufacturing and distribution capabilities. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers' and prospective customers' needs on a timely basis.

In addition, we have limited marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on attracting customers for our products and building brand loyalty. To successfully perform sales, marketing, distribution, and customer support functions ourselves, we face a number of risks, including:

- our ability to attract and retain the skilled support team, marketing staff and sales force necessary to commercialize and gain market acceptance for our technology and our products;
- the ability of our sales and marketing team to identify and penetrate the potential customer base, including hospitals, national and regional reference laboratories, group purchasing organizations, and integrated delivery networks; and
- the difficulty of establishing brand recognition and loyalty for our products.

Some hospital-based and reference laboratories may not consider adopting our instrument systems unless we offer a broader menu of diagnostic test panels or may choose not to convert from competitive products. In addition, in order to commercialize our products, we are required to undertake time consuming and costly development activities, including clinical studies for which the

outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to effectively compete, our revenues and our ability to achieve profitability will be significantly impaired.

We may not expand sales of our ePlex system outside the United States at the levels or within the time frame we anticipate.

We have obtained CE Mark for our ePlex Instrument and the following ePlex assays: the ePlex RP Panel, RP2, the ePlex BCID-GP Panel, the ePlex BCID-GN Panel, and the ePlex BCID-FP Panel. We are commercializing our ePlex system internationally via a network of distribution partners, which is augmented by a limited set of direct sales and technical support personnel. If we are unable to establish the infrastructure or recruit highly qualified personnel to support our international sales and support organization, if we fail to identify new distribution partners, or if we are unsuccessful in developing awareness and acceptance of our products and technology internationally, our anticipated revenue growth internationally may not materialize at the levels or within the time frame we expect, our customers may not receive the level of service or product dependability they expect from us, and our future financial performance may be adversely affected. Furthermore, the distributors we establish in particular geographic regions may not commit the necessary resources to market and sell our products to meet our expectations. If our distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or if we are unable to locate distributors in particular geographic areas, our ability to realize revenue growth based on sales outside the United States would be harmed. We also must comply with applicable foreign regulatory agency post-market requirements, including routine Notified Body conformity assessments to quality system standards (e.g., ISO 13485). Any failure to maintain post-market compliance with foreign regulatory requirements could harm our business, operations, and/or financial condition.

If our customers are not adequately reimbursed or compensated for the use of our products, we may have difficulty selling our products.

Our ability to sell our products depends in part on the extent to which reimbursement related to performing tests using our products is available from governmental authorities, such as Medicare and other domestic and foreign governmental programs, private insurance plans, managed care organizations, and other organizations. There are ongoing efforts by governmental and third party-payors to contain or reduce the costs of healthcare coverage. For example, a number of Medicare Administrative Contractors ("MACs") recently issued final local coverage determinations limiting or eliminating Medicare coverage for the use of certain multiplex molecular respiratory tests such as our ePlex RP and RP2 Panels and XT-8 Respiratory Viral Panel ("RVP") in an outpatient setting. As a result, this determination may negatively impact the use of our and certain of our competitors' multiplex respiratory tests within the geographic regions covered by these MACs. In addition, if other MACs and private payors take a similar approach, this potential negative impact could affect the available market for our ePlex RP Panel and XT-8 RVP Panel in additional geographic regions and patient populations. Furthermore, if our competitors are able to obtain product-specific reimbursement levels higher than those for our similarly situated products, or if the scope of coverage applicable to our competitors' products exceeds the scope of coverage applicable to our products, the overall demand for our products or the prices at which we are able to sell our products may be negatively impacted.

In addition, efforts to reform the healthcare delivery system in the United States and Europe have increased pressure on healthcare providers to reduce costs. For example, implementation of certain provisions of the Protecting Access to Medicare Act ("PAMA") in the United States had a negative impact on reimbursement payments from the Centers for Medicare and Medicaid Services ("CMS") for our diagnostics test panels paid under the Clinical Laboratory Fee Schedule ("CLFS"). Under these provisions of PAMA, payments under the CLFS are likely to be reduced annually for the next several years. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, either directly or indirectly, they may forego or reduce their purchase and use of our products or the price we may be able to charge for our products could be reduced.

Obtaining coverage and reimbursement approval for a product from each government or third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products to each government or third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs. Further, third-party payors may choose to reimburse our customers per test based on individual biomarker detection, rather than on the basis of the number of results given by the test panel. This may result in our customers electing to use separate tests to screen for each disease or condition so that they can receive reimbursement for each test they conduct. In that event, these entities may purchase separate tests for each disease, rather than products, such as ours, that can be used to return highly multiplexed test panel results.

If our products do not perform as expected our operating results and business would suffer.

Our success depends on the market's confidence that we can provide reliable, high quality, molecular diagnostic products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. As a result, our reputation and the public image of our products and technologies will be significantly impaired if our products fail to perform as expected. Although our diagnostic systems are designed to be user friendly, the functions they perform are complex and our products may develop or contain undetected defects or errors.

We currently manufacture our proprietary test cartridges at our Carlsbad, California manufacturing facilities. We outsource the manufacture of our ePlex instrument to Plexus, which specializes in the manufacturing of electronic and electro-mechanical devices. We currently maintain an inventory of XT-8 instruments and related components to satisfy the expected demand for our XT-8 system for the foreseeable future, as well as to service XT-8 instruments installed at customer locations. While we work closely with Plexus to ensure continuity of supply while maintaining high quality and reliability, and we believe our current stock of XT-8 instruments and related components will be sufficient for our and our customers' anticipated needs, we cannot guarantee that these efforts will be successful.

If we experience a material defect or error in any of our current or future products, it could result in the loss or delay of revenues, increased costs, delayed or reduced market acceptance, damaged reputation, diversion of development and management resources, legal and/or regulatory claims, recalls, increased insurance costs, or increased service and warranty costs, any of which could materially harm our business, financial condition, and results of operations.

We also face the risk of product liability exposure related to the sale of our products. We currently carry product liability insurance that covers us against specific product liability claims. We also carry a separate general liability and umbrella policy that covers us against certain claims but excludes coverage for product liability. Any claim in excess of our insurance coverage, or for which we do not have insurance coverage, would need to be paid out of our cash reserves, which would harm our financial condition. We cannot assure you that we have obtained sufficient insurance or broad enough coverage to cover potential claims. Also, we cannot assure you that we can or will maintain our insurance policies on commercially acceptable terms, or at all. A product liability claim could significantly harm our business, financial condition, and results of operations.

Our quarterly revenue and operating results may vary significantly and we may experience constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand.

Revenue from our infectious disease products fluctuates based upon the occurrence of related outbreaks and changes in testing recommendations and available therapies. For example, the recent COVID-19 pandemic has significantly increased the demand for our ePlex RP Panel, ePlex SARS-CoV-2 Test (sales of which we discontinued in the fourth quarter of 2020), and RP2. Influenza and other respiratory-related outbreaks are usually more concentrated in the first and fourth quarters of the year within the Northern hemisphere. New information or the introduction of advanced treatment options with respect to a particular disease may also affect the rate of related diagnostic testing. Although certain infectious disease outbreaks tend to occur each year, the timing, severity, and length of these incidents varies from one year to another and can vary across different patient populations. In addition, we may not accurately predict the impact of new therapies or vaccines on disease prevalence or changes to infectious disease testing recommendations affecting our products. As a result of one or more of these factors, we may not be able to accurately forecast sales from our infectious disease products.

Our revenue, results of operations, and cash flows would suffer upon the loss of a significant customer.

Sales to one customer accounted for approximately 10%, 14%, and 16% of our total revenue for the fiscal years ended December 31, 2020, 2019, and 2018, respectively. The loss of a significant customer or a significant reduction in the amount of product ordered by our significant customers may adversely affect our revenue, results of operations, and cash flows.

If we are unable to retain key employees or hire additional skilled employees, we may be unable to achieve our goals.

Our performance is substantially dependent on the performance of our senior management. Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. Our senior managers can terminate their relationship with us at any time. The loss of services of any of these key personnel could significantly reduce our operational effectiveness and investor confidence and our stock price could decline. We do not maintain key-man life insurance on any of our employees.

In addition, our product development and marketing efforts could be delayed or curtailed if we are unable to attract, train and retain highly skilled technical employees and scientific advisors. To expand our research, product development and commercial efforts, we will need to retain additional people skilled in areas such as electrochemical and molecular science, information technology, manufacturing, sales, marketing and technical support. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology. We may not be successful in hiring or retaining qualified personnel, and any failure to do so could have a material adverse effect on our business, financial condition and results of operations.

Accounting and Financial Risks

We may need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all.

Until such time, if ever, as we can generate positive cash flows from operations, we will be required to finance our operations with our cash resources and amounts made available under our credit facility. We may need to raise additional funds in the future to support our operations. We cannot be certain that additional capital will be available as needed, on acceptable terms, or at all. If we require additional capital at a time when investment in our company, in molecular diagnostics companies, or the marketplace in

general is limited, we may not be able to raise such funds at the time that we desire, or at all. If we do raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be significantly diluted. In addition, newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds through collaborations and licensing arrangements, we could be required to relinquish significant rights to our technologies and products, or grant licenses on terms that are not favorable to us.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which may be outside of our control. These factors include, but are not limited to:

- the time and resources required to develop, and conduct clinical studies and obtain regulatory clearances for, our diagnostic panels;
- the expenses we incur to increase our manufacturing capabilities, including costs to lease new facilities and expenses to purchase capital equipment and increase our manufacturing capacity and yield;
- the expenses we incur for research and development required to maintain and improve our technology, including developing new ePlex test menu;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including product marketing, sales, and distribution expenses;
- the expenses we incur in licensing technologies or securing rights to new products from third parties to expand the menu of products and services we plan to offer;
- our sales strategy and whether the revenues from sales of our test cartridges or systems will be sufficient to offset our expenses;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning manufacturing costs and yield and future revenues from sales of our products, as well as our assessment of the future investments needed to expand our commercial organization and manufacturing capabilities to support our anticipated revenue growth and research and development activities. We may be unable to reduce our expenditures in a timely manner, we may incur expenses for unexpected events, or we may experience a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected costs or events could have an immediate and material impact on our business and financial condition.

Our credit facility contains restrictions that limit our flexibility in operating our business.

We must comply with certain affirmative and negative covenants under our credit facility, including covenants that limit or restrict our ability to, among other things:

- incur additional indebtedness or issue certain preferred shares;
- pay dividends on, repurchase or make distributions in respect of, our capital stock or make other restricted payments;
- make certain investments or acquisitions;
- sell certain assets;
- create liens; or
- enter into certain transactions with our affiliates.

If we default under the agreement, because of a covenant breach or otherwise, the outstanding amounts thereunder could become immediately due and payable, and the lenders could terminate all commitments to extend further financing.

We have a history of net losses, and we may never achieve or maintain profitability.

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. Our net losses were approximately $18.6 million, $47.4 million, and $50.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $532.9 million. We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing operations, primarily related to expanding our commercial organization (sales and marketing) and manufacturing activities related to our ePlex system, maintaining our existing intellectual property portfolio, obtaining additional intellectual property rights, and investing in corporate infrastructure. We cannot provide any

assurance that we will achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our limited commercialization history and the rapidly evolving nature of our target market, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

Economic conditions and an uncertain economic outlook may adversely impact our business, results of operations, financial condition or liquidity.

Global economic conditions may remain challenging and uncertain for the foreseeable future, particularly in light of the recent COVID-19 pandemic. These conditions may not only limit our access to capital but also make it extremely difficult for our customers, our vendors, and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign businesses and consumers to experience operating disruptions or slow spending on our products and services, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government's allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers, increase our allowance for doubtful accounts, and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we may not continue to experience the same loss rates that we have in the past. Additionally, these economic conditions and market turbulence may also impact our suppliers, causing them to be unable to supply sufficient quantities of customized components in a timely manner, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

We are exposed to risks associated with long-lived and intangible assets that may become impaired and result in an impairment charge.

The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. These events or changes might include an inability to successfully deliver an instrument to the marketplace and attain customer acceptance, a change in the rights or use of licensed intellectual property, adjustments to our depreciation assumptions, or other matters. Adverse events or changes in circumstances may affect the estimated discounted future cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Providing instrument systems to our customers through reagent rental agreements may harm our liquidity.

Many of our systems are provided to customers via "reagent rental" agreements, under which customers are generally afforded the right to use the instrument in return for a commitment to purchase minimum quantities of reagents and test cartridges over a period of time. Accordingly, we must either incur the expense of manufacturing instruments well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our instrument. The amount of capital required to provide instrument systems to customers depends on the number of systems placed. Our ability to generate capital to cover these costs depends on the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we cannot sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2020, we had pre-2018 net operating loss ("NOL"), carryforwards available of approximately $264.0 million for U.S. federal income tax purposes. The federal NOL carryforwards generated prior to 2018 will begin to expire in 2025. The NOLs generated in 2018 and 2019 of $77.8 million will carry forward indefinitely and be available to offset up to 80% of future taxable income each year.

Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), generally imposes an annual limitation on the amount of NOL carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in stock ownership. We have determined that we have experienced multiple ownership changes under Section 382 of the Code. Our ability to use the current federal and state NOL carryforwards may also be limited by the issuance of common stock in the future. To the extent our use of federal and state NOL carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use the state or federal NOL carryforwards. We have recorded a full valuation allowance against our federal and state net deferred tax assets.

We also had state NOL carryforwards of approximately $243.7 million as of December 31, 2020. We have recorded a full valuation allowance against our net deferred tax assets.

Regulatory, Legislative, and Legal Risks

The regulatory clearance or approval process for certain products is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from commercializing our products.

We obtained 510(k) clearance from the FDA for our ePlex Instrument and the following ePlex assays: the ePlex RP Panel; the ePlex BCID-GP Panel; the ePlex BCID-GN Panel; and the ePlex BCID-FP Panel. We are also commercializing our ePlex RP2 Panel under EUA. We are investing significantly in the development of new ePlex molecular diagnostic tests to expand our future product offerings, including our ePlex Gastrointestinal Pathogen Panel, which will require clinical studies and subsequent 510(k) clearance, pre-market approval, or EUA by the FDA prior to marketing those tests for commercial use in the United States. There are a number of potential risks associated with conducting clinical studies and obtaining regulatory clearance. For example, we may have difficulty maintaining the level of reliability and clinical accuracy required to complete clinical studies and obtain FDA clearance or approval. In addition, the FDA may require that we conduct additional studies that could impact the cost associated with product clearance and could potentially delay commercial launch of new ePlex molecular diagnostic tests in the United States. We may be unsuccessful in obtaining FDA clearance for our expanding ePlex test menu within our expected time frame, or at all, which could adversely impact our future financial performance and cause our stock price to decline.

The regulatory environment is constantly evolving. For example, the FDA conducted a review of the pre-market clearance process in response to internal and external concerns regarding the 510(k) program and, in January 2011, announced 25 action items designed to make the process more rigorous and transparent. Some of these proposals, if enacted, could impose additional regulatory requirements for device manufacturers which could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances. Similarly, the European Union (“EU”), is transitioning from the existing European Directive 98/79/EC on in vitro diagnostic medical devices, or IVD Directive (“IVDD”), to the In Vitro Diagnostic Device Regulation (“IVDR”). Specifically, the IVDR repeals and replaces the IVDD. Unlike the directive, which must be implemented into the national laws of the European Economic Area (“EEA”), Member States, the IVDR is directly applicable in all EEA Member States and is intended to eliminate current differences in regulation of IVDs among EEA Member States. Under the IVDR, the classifications of our molecular diagnostic products are impacted, and will result in additional regulatory requirements, which could delay our ability to CE Mark our products. Delays in receipt of, or failure to obtain, clearances or approvals for future products would result in delayed, or no, realization of revenues from such products and in substantial additional costs, which could decrease our profitability.

We must also comply with the applicable FDA and foreign regulatory agency post-market requirements, including routine Notified Body conformity assessments to quality system standards (e.g., ISO 13485). Any failure to maintain post-market compliance with FDA or foreign regulatory requirements could harm our business, operations, and/or financial condition.

We derive revenues from the sale of research use only (RUO) tests and custom manufactured reagents, which are not intended for diagnostic purposes. Clinical laboratories are regulated under CLIA and may validate the clinical diagnostic use of an LDT specifically for use in their laboratory using any labeled products. While the FDA has traditionally practiced enforcement discretion regarding the use of the LDTs for clinical diagnostic purposes, there have been regulatory actions indicating a potential change in enforcement practices (e.g., the FDA has promulgated draft guidance which outlines stringent regulatory requirements for CLIA labs to use LDTs for clinical diagnostic application and the FDA has issued warning letters to labs marketing the clinical utility of LDTs). These proposed requirements, if implemented, may result in a significant reduction in the sale of our RUO or custom manufactured products, which could reduce our revenues and adversely affect our operations and/or financial condition.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

Our commercial, research, and other financial relationships with healthcare providers and institutions are subject to various federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the knowing offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid, or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The False Claims Act (“FCA”) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. We have implemented procedures designed to ensure our compliance with relevant legal requirements. Nevertheless, if our marketing, sales, or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related

laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

The Health Care Act also imposes reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. In February 2013, the Centers for Medicare and Medicaid Services ("CMS"), released the final rule implementing the federal Physician Payments Sunshine Act (the "Sunshine Act"). The law requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals. These reporting requirements took effect on August 1, 2013. Failure to submit required information may result in significant civil monetary penalties.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts, and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increases the possibility that a healthcare company may run afoul of one or more of the requirements.

We are also subject to the U.S. Foreign Corrupt Practices Act (the "FCPA"), and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents, or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition, and results of operations.

Legislative or regulatory healthcare reforms may have a material adverse effect on our business and results of operations.

Federal and state governments in the United States are undertaking efforts to control growing health care costs through legislation, regulation, and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted the Patient Protection and Affordable Care Act (the "PPACA"). While the PPACA involves expanding coverage to more individuals, it includes regulatory mandates and other measures designed to constrain medical costs. Among other requirements, the PPACA imposes a 2.3% excise tax on sales of medical devices by manufacturers. In December 2015, the excise tax was suspended for 2016 and 2017, and, in January 2018, the excise tax was further suspended until 2020. Taxable devices include certain medical devices intended for use by humans, with limited exclusions for retail devices purchased by the general public for individual use. There is no exemption for small companies, and we paid the tax from 2013 through 2015. Recently, Congress and the administration have proposed and taken various steps to revise, repeal, or delay implementation of various aspects of PPACA. If the PPACA is significantly revised, repealed, or if implementation of various aspects are delayed, such modification, repeal, or delay may impact our business, financial condition, results of operations, cash flows, and the trading price of our securities. Complying with PPACA may significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

The Budget Control Act of 2011 provided, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. In addition to the potential impacts to PPACA under the current administration, there could be sweeping changes to the Budget Control Act and other healthcare reforms. For example, the Tax Cuts and Jobs Act enacted in December 2017 eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional changes to the PPACA remain possible. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Both within and outside the United States, we are impacted by privacy and data security requirements at the international, national, and regional level, and on an industry-specific basis. More privacy and security laws and regulations are being adopted, and more are being enforced, with the potential for significant financial penalties. In the European Union ("EU"), increasingly stringent data protection and privacy rules have been enacted. The EU General Data Protection Regulation ("GDPR") applies uniformly across the EU and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances. The GDPR also requires companies processing personal data of individuals residing in the EU to comply with EU privacy and data protection rules. The State of California has also enacted a consumer privacy law which imposes similar data privacy and security requirements. Our failure to maintain the confidentiality and security of sensitive personal information in accordance with applicable regulatory requirements could subject us to financial penalties and breach of contract claims and could damage our reputation.

Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.

Our commercial success depends on our ability to develop, manufacture, and market our systems and tests and use our proprietary technology without infringing the patents and other proprietary rights of third parties. As the molecular diagnostics industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we must challenge to continue our operations as currently contemplated. Our products may infringe or may be alleged to infringe these patents.

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, three Supreme Court cases, Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al., Mayo Collaborative Services v. Prometheus Laboratories, and Alice v. CLS Bank, have introduced additional questions regarding the patentability of isolated naturally occurring genes and gene fragments, proteins, peptides, natural products, and related diagnostic and therapeutic methods, which are likely to be resolved only through continued litigation. The overall impact of these decisions and others on the molecular diagnostics industry remains uncertain and our interpretation of the scope of these rulings on existing or future patents may be inaccurate.

There is a significant amount of uncertainty regarding the extent of patent protection and infringement. Companies may have filed pending patent applications that cover technologies we incorporate in our products. As a result, we could be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights. Even if we are successful in defending against potential intellectual property infringement claims, we could incur substantial costs in doing so. Any litigation related to such claims could consume our resources and lead to significant damages, royalty payments, or an injunction on the sale of certain products. Any additional licenses to patented technology could obligate us to pay substantial additional royalties, which could adversely impact our product costs and harm our business.

If we are unable to obtain, maintain, and enforce intellectual property protection covering our products, others may be able to make, use, or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.

Our commercial success is dependent in part on obtaining, maintaining, and enforcing intellectual property rights, including our patents, key licenses, and other intellectual property rights. If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products that are substantially the same as ours without incurring the sizable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that compete with our products. Currently, our patent portfolio is comprised on a worldwide basis of more than 100 owned and licensed patents and approximately 25 additional pending patent applications. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. Several of our pending applications have the potential to mature into patents that may expire between 2029 and 2039. However, not all of the pending or future patent applications owned by or licensed to us are guaranteed to mature into patents, and, moreover, issued patents owned by or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

We also rely on trade-secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. We have limited control over the protection of trade secrets used by our licensors, collaborators, and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is difficult, expensive, and time consuming, and the outcome is unpredictable. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants, and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

We and our suppliers, contract manufacturers, and customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these regulations.

Our manufacturing processes and facilities and those of some of our contract manufacturers must comply with QSR and certain foreign regulatory requirements, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of our devices. The FDA and other foreign regulatory bodies enforce the QSR

and similar foreign regulatory requirements through periodic announced and/or unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies.

We must also file reports of device corrections and removals and adhere to the domestic and foreign rules on labeling and promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Failure to comply with applicable regulatory requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our contract manufacturers to take satisfactory corrective action in response to an adverse regulatory inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our products;
- total or partial suspension of production or distribution;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the import or export of our products; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from marketing, distributing, or selling our products and would likely harm our business.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a reasonable risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our common stock to decline and expose us to product liability or other claims, including contractual claims from parties to whom we sold products, and harm our reputation with customers.

The use of our diagnostic products by our customers is also affected by CLIA and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance, quality control, and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories from using some or all of our diagnostic products.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, and failure to comply with these laws could harm our business and the price of our common stock.

As a public company listed in the United States, we incur significant legal, accounting, and other expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC, the Public Company Accounting Oversight Board (“PCAOB”), and The NASDAQ Global Market, may increase our legal and financial compliance costs and make some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If we nevertheless fail to comply with new laws, regulations, and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

We use hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research, product development and manufacturing processes involve the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resulting injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal

of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Our operations are regulated and may require that environmental permits and approvals be issued by applicable government agencies. Compliance with environmental laws and regulations may be expensive and may impair our research, development and production efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

Provisions of our certificate of incorporation, our bylaws, and Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our certificate of incorporation and bylaws could discourage, delay, or prevent a merger, acquisition, or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- provide that our stockholders may remove our directors only for cause;
- establish a classified board of directors, such that not all members of the Board of Directors may be elected at one time;
- authorize our Board of Directors to issue without stockholder approval up to 100,000,000 shares of common stock, that, if issued, would dilute our stock ownership and could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- authorize our Board of Directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Information Technology Risks

Cyberattacks and other security breaches could compromise our proprietary information which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is critical to our operations, business strategy, and reputation. Computer hackers may attempt to penetrate our computer systems or our third party IT service providers' systems and, if successful, misappropriate our proprietary information. In addition, an employee, contractor, or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we will continue to implement additional protective measures to reduce the risk of and detect cyberattacks, these incidents are becoming more sophisticated and frequent, and the techniques used in such attacks evolve rapidly and are difficult to detect. Despite our cybersecurity measures, our information technology networks and infrastructure may still be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our, or our third party IT service providers' data security and access to, or public disclosure or loss of, confidential business or proprietary intellectual property information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

Information technology systems implementation issues could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays, or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an enterprise resource planning software system. To more fully realize the potential of this system, we are continually reassessing and upgrading processes and this may be more expensive, time consuming, and resource intensive than planned. Any disruptions that may occur in the operation of this system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position, and cash flows and to otherwise operate our business in a secure environment, all of which could adversely affect our financial results, stock price, and reputation.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently operate from three facilities located in Carlsbad, California. We do not own any real property. In February 2010, we entered into a lease for an approximately 31,000 square foot facility in Carlsbad, California, the term of which originally ran through September 2017. The facility is part of a three-building office and research and development project located at 5964 La Place Court, Carlsbad, California. In January 2012, we signed a lease amendment which expanded our executive and administrative office, research and development, and manufacturing space by approximately 22,000 additional square feet. The lease term expires in June 2025.

Our other facilities are located at nearby locations in Carlsbad, California, and are primarily used for ePlex manufacturing operations, research and development, and distribution purposes. In June 2015, we leased an additional 34,000 square foot facility which as a lease term that runs through September 2023 and has an option to extend the term of the lease for an additional five years. In July 2020, we leased an additional 73,000 square foot facility which has a lease term that runs through June 30, 2031. We believe our existing properties are in good condition and are sufficient and suitable for the conduct of our business.

ITEM 3. LEGAL PROCEEDINGS

We are from time to time subject to various claims and legal actions in the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on the NASDAQ Capital Market under the ticker symbol "GNMK."

Stockholders

As of February 22, 2021, there were 742 stockholders of record of our common stock and an undetermined number of beneficial owners.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not expect to pay any dividends for the foreseeable future. In addition, our credit facility contains a negative covenant which may limit our ability to pay dividends. We currently intend to retain any future earnings to fund the operation, development, and expansion of our business. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon a number of factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in our current and future debt arrangements, and other factors our Board of Directors may deem relevant. Our ability to declare dividends is restricted by our Loan and Security Agreement with Solar Capital Ltd.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 201(d) of Regulation S-K is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data relates to GenMark Diagnostics, Inc. and its consolidated subsidiaries. The selected consolidated statement of comprehensive loss data presented below of GenMark Diagnostics, Inc. for the years ended December 31, 2020, 2019, and 2018 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2020 and 2019 have been derived from the audited consolidated financial statements of GenMark Diagnostics, Inc., which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), included elsewhere in this Annual Report. The selected consolidated statement of comprehensive loss data presented for the years ended December 31, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 2018, 2017, and 2016 have been derived from audited financial statements not included in this Annual Report.

The results for the periods shown below are not necessarily indicative of the results to be expected for any future periods. The selected consolidated financial data should be read in conjunction with Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report.

Selected Financial Data

(in thousands, except per share data)

	Year ended December 31,				
	2020	**2019**	**2018**	**2017**	**2016**
Income Statement Data:					
Revenue	$ 171,554	$ 88,021	$ 70,759	$ 52,519	$ 49,274
Gross profit	$ 67,944	$ 28,603	$ 19,481	$ 20,005	$ 29,574
Loss from operations	$ (11,051)	$ (41,814)	$ (47,772)	$ (59,517)	$ (48,981)
Net loss	$ (18,644)	$ (47,350)	$ (50,500)	$ (61,850)	$ (50,601)
Net loss per share—basic and diluted	$ (0.28)	$ (0.82)	$ (0.91)	$ (1.21)	$ (1.15)
Balance Sheet Data:					
Cash and cash equivalents and marketable securities [1][2][3][4]	$ 128,154	$ 53,460	$ 45,168	$ 71,990	$ 41,566
Total assets	$ 223,534	$ 111,473	$ 92,981	$ 122,299	$ 80,324
Long-term liabilities	$ 85,206	$ 74,994	$ 39,147	$ 23,399	$ 15,752
Total liabilities	$ 129,336	$ 99,310	$ 59,434	$ 51,142	$ 42,173
Accumulated deficit	$ (532,877)	$ (514,233)	$ (466,883)	$ (416,383)	$ (355,270)
Total stockholders' equity [1][2][3][4]	$ 94,198	$ 12,163	$ 33,547	$ 71,157	$ 38,151

(1) In May 2020, we issued approximately 8.3 million shares of common stock at an average price of $9.65 per share. We raised approximately $75.4 million in net proceeds.

(2) During the five months ended December 31, 2019, we issued approximately 2.3 million shares of common stock at an average price of $5.77 per share. We raised approximately $12.5 million in net proceeds.

(3) In June 2017, we issued approximately 7.3 million shares of common stock at a price of $11.75 per share. We raised approximately $80.7 million in net proceeds.

(4) In August and September 2016, we issued approximately 3.3 million shares of common stock at an average price of $9.04 per share. We raised approximately $28.9 million in net proceeds.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following in conjunction with the "Selected Consolidated Financial Data" and the consolidated financial statements of GenMark and the related notes thereto that appear elsewhere in this Annual Report. In addition to historical information, the following discussion and analysis includes forward looking information that involves risks, uncertainties, and assumptions. Actual results and the timing of events could differ materially from those anticipated by these forward looking statements as a result of many factors, including those discussed under the heading "Risk Factors" included elsewhere in this Annual Report. See also "Forward Looking Statements" included elsewhere in this filing.

Overview

GenMark is a molecular diagnostics company focused on developing and commercializing multiplex solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. We currently develop and commercialize high-value, simple to perform, clinically relevant multiplex molecular tests based on our proprietary eSensor electrochemical detection technology.

Since inception, we have incurred net losses from operations each year, and we expect to continue to incur losses for the foreseeable future. Our net losses for the years ended December 31, 2020, 2019, and 2018 were approximately $18.6 million, $47.4 million, and $50.5 million, respectively. As of December 31, 2020, we had an accumulated deficit of $532.9 million. Our operations to date have been funded principally through sales of capital stock, borrowings, and cash from operations.

Our Products and Technology

We offer our ePlex sample-to-answer instrument and Respiratory Pathogen ("RP") Panel, Respiratory Pathogen Panel 2 ("RP2"), Blood Culture Identification Gram-Positive ("BCID-GP") Panel, Blood Culture Identification Gram-Negative ("BCID-GN") Panel, and Blood Culture Identification Fungal Pathogen ("BCID-FP") Panel for sale in the United States and internationally. In addition, in response to the COVID-19 outbreak, we received Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA"), in March 2020 for our ePlex SARS-CoV-2 Test. We discontinued sales of our ePlex SARS-CoV-2 Test in the fourth quarter of 2020. We also received CE Mark and FDA EUA for RP2, which is designed to provide results for SARS-CoV-2 in addition to the other respiratory viruses contained on our ePlex RP Panel. We are also developing our ePlex Gastrointestinal Pathogen ("GI") Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

We offer four FDA-cleared diagnostic tests which run on our XT-8 instrument: our Respiratory Viral Panel; our Cystic Fibrosis Genotyping Test; our Warfarin Sensitivity Test; and our Thrombophilia Risk Test. We also offer a Hepatitis C ("HCV") Genotyping Test and associated custom manufactured reagents, as well as a 2C19 Genotyping Test, each of which is available for use with our XT-8 instrument for research use only ("RUO"). In addition, in August 2020 we submitted an EUA to the FDA for our eSensor SARS-CoV-2 Test.

COVID-19 Impact

Our priorities following the COVID-19 outbreak have been, among others, protecting the health and safety of our employees; and increasing our manufacturing capacity for our ePlex tests including RP2, which includes the SARS-CoV-2 pathogen target, and the SARS-CoV-2 single target test in order to assist our customers with the current pandemic. We discontinued the sale of our ePlex SARS-CoV-2 test in the fourth quarter of 2020. We continued to expand our manufacturing capacity to address demand for our tests.

During the year ended December 31, 2020, portions of our workforce worked remotely as their positions allowed. Our ability to continue to operate without any significant negative operational impact from the COVID-19 pandemic will, in part, depend on our ability to protect our employees and maintain our supply chain. We continue to endeavor to follow the recommended actions of government and health authorities to protect our employees, with particular measures in place for employees who manufacture our products. However, the complications resulting from the pandemic could result in unforeseen disruptions to our workforce and supply chain (for example, the inability of a key supplier or transportation supplier to source, transport and supply materials to us that are necessary for continued operations) that could negatively impact our operations.

We believe the extent of the COVID-19 pandemic's impact on our operating results and financial condition will be driven by many factors, most of which are beyond our control and ability to forecast. Such factors include, but are not limited to, the severity and duration of the pandemic, our ability to timely develop, commercialize and manufacture solutions related to the pandemic, the extent and the effectiveness of responsive actions taken by authorities of impacted countries, the impact of these and other factors on our employees, customers and suppliers, as well as any resulting impact of the economic uncertainty and volatility that could affect demand for our products. Because of these and other uncertainties, we cannot estimate the length or extent of the impact of the pandemic on our business. For additional information on risk factors related to the pandemic or other risks that could impact our results, please refer to "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

Revenue

Revenue from operations includes revenue from the sale of our products and other services. Product revenue comprises the sale of diagnostic tests and instruments. In addition to selling our instruments, we also place our instruments with customers through a reagent rental agreement, under which we retain title to the instrument and customers generally commit to purchasing minimum quantities of reagents and test cartridges over a period of one to five years. Under our reagent rental agreements, a portion of the price charged to customers from the sale of test cartridges is attributable to the usage fee for the instrument. Other revenue primarily consists of freight revenue and revenue from extended service agreements.

Cost of Revenues

Cost of revenues includes the cost of materials, direct labor, and manufacturing overhead costs used in the manufacture of our consumable tests. Cost of revenues also includes depreciation on revenue generating instruments that have been placed with our customers under a reagent rental agreement, cost of instruments sold to customers, amortization of licenses related to our products, and other costs such as warranty, royalty, and customer and product technical support. Any potential underutilized capacity may result in a high cost of revenues relative to revenue, if manufacturing volumes are not able to fully absorb operating costs. Our instruments are procured from contract manufacturers. We expect our cost of revenues to increase as we place additional instruments and manufacture and sell additional diagnostic panels; however, over time, we expect our cost per unit to decrease as production volume increases, manufacturing efficiencies are realized, improvements to procurement practices are made, product reliability increases, and other improvements decrease costs.

Sales and Marketing Expenses

Sales and marketing expenses include costs associated with our direct sales force, sales management, marketing, customer support, and business development activities. These expenses primarily consist of salaries, commissions, benefits, stock-based compensation, travel, advertising, promotions, product samples, and trade show expenses.

Research and Development Expenses

Research and development expenses primarily include costs associated with the development and expansion of our ePlex instrument’s diagnostic test menu. These expenses also include certain clinical study expenses incurred in preparation for FDA clearance for these products, intellectual property prosecution and maintenance costs, and quality assurance expenses. The expenses primarily consist of salaries, benefits, stock-based compensation, outside design and consulting services, laboratory supplies, costs of consumables and materials used in product development, and clinical studies and facility costs. We expense all research and development expenses in the periods in which they are incurred.

General and Administrative Expenses

Our general and administrative expenses include costs associated with our executive, accounting and finance, compliance, information technology, legal, facilities, human resources, administrative, and investor relations activities. These expenses consist primarily of salaries, benefits, stock-based compensation, independent auditor costs, legal fees, consultant costs, insurance premiums, and public company expenses, such as stock transfer agent fees and listing fees for NASDAQ.

Foreign Exchange Gains and Losses

Transactions in currencies other than our functional currency, the U.S. Dollar, are translated at the prevailing rates on the dates of the applicable transaction. Foreign exchange gains and losses arise from differences in exchange rates during the period between the date a transaction denominated in a foreign currency is consummated and the date on which it is settled or translated.

Interest Income and Interest Expense

Interest income includes interest earned on our cash and cash equivalents and investments. Interest expense represents interest incurred on our loan payable and on other liabilities.

Provision for Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income, and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance. If it is more likely than not that we will not recover our deferred tax assets, we will increase our provision for income taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable.

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential adjustments and adjust the income tax provision, income taxes payable, and deferred taxes in the period in which the facts that give rise to a revision become known.

Results of Operations—Comparison of Years ended December 31, 2020, 2019, and 2018 (*dollars in thousands*):

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Revenue	$ 171,554	$ 88,021	$ 70,759	$ 83,533	95 %	$ 17,262	24 %

Our revenue consists primarily of revenue from the sale of test cartridges (which we refer to as consumables), instruments, and other revenues.

Revenue increased by $83.5 million, or 95%, when comparing the years ended December 31, 2020 and 2019, primarily driven by growth in ePlex product revenue. For the year ended December 31, 2020, ePlex product revenue increased by $92.8 million, or 155%, to $152.6 million primarily due to increases in the sale of RP2 and SARS-CoV-2 test consumables and instrument sales to both new and existing customers. XT-8 product revenue decreased by $10.5 million over the prior year period, or 39%, to $16.6 million during the year ended December 31, 2020, primarily due to XT-8 customers that converted to our ePlex system for respiratory testing.

Revenue increased by $17.3 million, or 24%, when comparing the years ended December 31, 2019 and 2018, primarily driven by growth in ePlex product revenue which features a higher selling price than our XT-8 system due to the additional technology and features of its sample-to-answer capabilities. For year ended December 31, 2019, ePlex product revenue increased by $22.2 million, or 59%, to $59.8 million due to new customers adopting the ePlex system for respiratory and blood stream infection testing. ePlex product revenue represented 69% of total product revenue during the year ended December 31, 2019. XT-8 product revenue decreased by $5.3 million to $27.0 million during the year ended December 31, 2019, primarily due to XT-8 customers that converted in 2018 to our ePlex system for respiratory testing.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Cost of revenue	$ 103,610	$ 59,418	$ 51,278	$ 44,192	74 %	$ 8,140	16 %
Gross profit	$ 67,944	$ 28,603	$ 19,481	$ 39,341	138 %	$ 9,122	47 %
Gross margin	39.6%	32.5%	27.5%				

The increase in cost of revenue for the year ended December 31, 2020, compared to the prior year was a result of the growth in ePlex product revenue, which increased by 155% when compared to the prior year and represented 90% of total product revenue during the period. Standard product costs increased by $39.7 million over the prior year due to increases in ePlex product revenue. Cost of revenue also increased by $3.4 million in royalties expense, $0.9 million in freight expense, $0.5 million in customer and product technical support expense, and $0.4 million in instrument repair expense, all as a result of the increases in ePlex product revenue. These increases were offset by decreases of $0.3 million attributable to the realization of manufacturing efficiencies and improvements to overhead absorption and $0.2 million in inventory reserve expense when compared to the prior year.

Gross profit increased by $39.3 million, or a gross margin increase of seven percentage points during the year ended December 31, 2020, when compared to the prior year, primarily due to the increase in revenue. The increase in gross margin to 39.6% in the current period was attributable to continued gains in efficiency in the manufacture of ePlex consumables as well as changes in the composition of ePlex product revenue. ePlex instrument sales also comprised a higher percentage of total product revenue and contributed to increased gross profit during 2020 when compared to the prior year.

The increase in cost of revenue for the year ended December 31, 2019, when compared to the prior year, is primarily a result of the growth in ePlex product revenue. ePlex revenue increased by 59% when compared to the prior year and represented 69% of total product revenue during the period. The increase in ePlex sales resulted in increased standard product costs of $12.5 million over the prior year as ePlex products carry higher cost profiles due to the enhanced technology and features as compared to XT-8 and corresponding higher average selling prices. Other cost of revenue increased due to increases of $1.1 million in inventory reserves expense and $0.8 million from increased royalties expense resulting from higher product revenue.

Gross profit increased by $9.1 million, or a gross margin increase of five percentage points during the year ended December 31, 2019, when compared to the prior year driven entirely by improvements to ePlex gross margin. These increases are the result of continued production gains in the manufacture of ePlex consumables. The increase in gross margin to 32.5% was attributable to decreased costs of $5.8 million due to improved overhead cost absorption and the realization of manufacturing efficiencies and $0.6 million from decreased warranty and customer and product technical support expenses.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Sales and marketing	$ 23,164	$ 24,118	$ 21,777	$ (954)	(4)%	$ 2,341	11 %

The decrease in sales and marketing expense for the year ended December 31, 2020, when compared to the prior year, was primarily driven by decreases of $1.2 million in evaluation kit expense resulting from the commercial launch of our ePlex BCID Panels during the prior year, $1.2 million in travel expense, $0.3 million in bad debt expense, $0.3 million in depreciation expense, and $0.1 million in marketing expense. These decreases were partially offset by increases of $2.2 million in personnel expense.

The increase in sales and marketing expense for the year ended December 31, 2019, when compared to the prior year, was primarily driven by increases of $1.5 million in personnel expense, $0.6 million in evaluation kits expense resulting from new ePlex system evaluations, and $0.3 million in higher allocated facility and information technology expense resulting from increased headcount.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
General and administrative	$ 25,572	$ 19,159	$ 17,545	$ 6,413	33 %	$ 1,614	9 %

The increase in general and administrative expense for the year ended December 31, 2020, when compared to the prior year, was primarily driven by $4.0 million in costs related to severance payments and stock-based compensation expense resulting from the departure of our former CEO in 2020, as well as increases of $1.0 million in legal related expenses, $0.8 million in professional services expense, and $0.5 million in supplies expense.

The increase in general and administrative expense for the year ended December 31, 2019, when compared to the prior year, was primarily related to increases of $1.1 million in personnel expense, including $0.8 million in stock-based compensation expense, and $0.5 million in higher facility and information technology expense.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Research and development	$ 30,259	$ 27,140	$ 27,931	$ 3,119	11 %	$ (791)	(3)%

The increase in research and development expense for the year ended December 31, 2020, when compared to the prior year, was primarily driven by increases of $2.8 million in personnel expense and $1.0 million increase in prototype materials used by our assay development teams, partially offset by a reduction in expense of $0.7 million related to a grant from BARDA received in the current period.

The decrease in research and development expense for the year ended December 31, 2019, when compared to the prior year, was primarily driven by a decrease of $1.5 million in clinical study expense based upon the timing of the completed ePlex BCID clinical studies, which was partially offset by a $0.7 million increase in prototype materials used by our assay development teams.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Other expense	$ (7,512)	$ (5,472)	$ (2,589)	$ (2,040)	37 %	$ (2,883)	111 %

Other expense represents non-operating income and expense, including, but not limited to, earnings on cash, cash equivalents, restricted cash, marketable securities, exchange gains and losses of foreign currency denominated balances, and interest expense related to debt.

The increases in other expense in each of the years ended December 31, 2020 and 2019 were primarily due to higher interest expense from borrowings from our loan and security agreement.

	Years Ended December 31,			2020 vs 2019		2019 vs 2018	
	2020	2019	2018	$ Change	% Change	$ Change	% Change
Income tax expense	$ 81	$ 64	$ 139	$ 17	27 %	$ (75)	(54)%

Due to net losses incurred, we have only recorded tax provisions related to minimum tax payments in the United States and tax liabilities generated by our foreign subsidiaries, which have remained immaterial.

Liquidity and Capital Resources

To date, we have funded our operations primarily from the sale of our common stock, borrowings, and cash from operations. We have incurred net losses from continuing operations each year and have not yet achieved profitability. As of December 31, 2020, we had $128.8 million of working capital, including $128.2 million in cash, cash equivalents, and marketable securities. We believe our existing cash, cash equivalents, and marketable securities as of December 31, 2020 will enable us to fund our operations for at least one year from the date this Annual Report on Form 10-K is filed with the SEC.

The following table summarizes, for the periods indicated, selected items in our consolidated statements of cash flows (*dollars in thousands*):

	Years Ended December 31,		
	2020	2019	2018
Net cash provided by (used in) operating activities	$ 6,134	$ (34,926)	$ (32,512)
Net cash provided by (used in) investing activities	(96,509)	(2,172)	33,947
Net cash provided by financing activities	87,570	45,173	8,069
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(95)	(1)	28
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (2,900)	$ 8,074	$ 9,532

Cash Flows from Operating Activities

Net cash provided by operating activities increased by $41.1 million for the year ended December 31, 2020, when compared to the prior year. The increase in cash provided by operating activities was primarily due to a decrease of $28.7 million in net loss, favorable changes in operating assets and liabilities of $11.7 million, and an increase of $0.6 million in non-cash adjustments. The changes in operating assets and liabilities was primarily a result of increases in accounts payable, accrued compensation, operating lease liabilities, and other liabilities, and a decrease in accounts receivable. These favorable changes were partially offset by an increase in inventory.

Net cash used in operating activities increased by $2.4 million for the year ended December 31, 2019, when compared to the prior year. The increase in cash used in operating activities was primarily due to unfavorable changes in operating assets and liabilities of $8.9 million, partially offset by a decrease of $3.2 million in net loss and an increase of $3.4 million in non-cash adjustments. The changes in operating assets and liabilities was primarily a result of increases in accounts receivable and inventory due to the growth of ePlex product revenue, a decrease in accrued compensation, and an increase in prepaid expenses and other current assets. These unfavorable changes were partially offset by an increase in accounts payable due to the timing of our payments and an increase in other liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities increased by $94.3 million for the year ended December 31, 2020, when compared to the prior year, primarily due to increases of $82.1 million in purchases of marketable securities and $15.7 million in purchases of property and equipment. These increases were partially offset by a decrease of $3.4 million in the sale and maturities of marketable securities.

Net cash used in investing activities increased by $36.1 million for the year ended December 31, 2019, when compared to the prior year, primarily due to a decrease of $34.2 million in the sale and maturities of marketable securities and an increase of $2.4 million in purchases of marketable securities. The increases in net cash used in investing activities were partially offset by a decrease of $0.5 million in purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities increased by $42.4 million for the year ended December 31, 2020, when compared to the prior year, primarily due to increases of $65.2 million in net proceeds from the issuance of common stock and $8.6 million from stock option exercises. The increase in cash provided by financing activities was partially offset by a decrease of $31.4 million from net payments on borrowings under our loan and security agreement.

Net cash provided by financing activities increased by $37.1 million for the year ended December 31, 2019, when compared to the prior year, primarily due to increases of $24.3 million in net proceeds from borrowings under our loan and security agreement, $12.4 million in net proceeds from the issuance of common stock, and $0.4 million from stock option exercises.

We have prepared cash flow forecasts which indicate, based on our current cash resources available, that we will have sufficient resources to fund our business for at least the next 12 months. Factors that could affect our capital requirements, in addition to those previously identified, include, but are not limited to:

- the level of revenues and the rate of our revenue growth;
- changes in demand from our customers;
- the level of cost of revenues and their impact to our gross margin;
- the level of expenses required to expand our commercial (sales and marketing) activities;
- the level of research and development investment required to develop our diagnostic systems and test menu;
- our need to acquire or license complementary technologies;
- the costs of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights;
- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

Loan and Security Agreement

On February 1, 2019 (the "Effective Date"), we entered into a Loan and Security Agreement (the "LSA"), with Solar Capital Ltd. and certain other financial institutions (collectively, the "Lenders"). Pursuant to the LSA and certain subsequent amendments, the Lenders have provided us with $70.0 million in a series of term loans, of which $50.0 million was funded on the Effective Date and an additional $20.0 million was funded in December 2019 upon our achievement of a designated amount of product revenues on a trailing six-month basis.

The term loans under the LSA accrue interest at a floating per annum rate in effect from time-to-time equal to (a) the greater of 2.51% or the one-month Intercontinental Exchange Benchmark Administration, Ltd. rate then in effect as of the applicable payment date, plus (b) 5.90% per annum. We are only required to make interest payments on amounts borrowed pursuant to the term loans from the applicable funding date until February 28, 2022 (the "Interest Only Period"). Following the Interest Only Period, monthly installments of principal and interest under the term loans will be due until the original principal amount and applicable interest is fully repaid by February 1, 2023.

Pursuant to the terms of the LSA, the Lenders are granted a security interest in (a) all of our personal property, other than intellectual property (which is subject to a negative pledge), but including our rights to payment in respect of intellectual property, and (b) the stock of all of our subsidiaries; provided that if the pledge of 100% of the voting shares of our non-U.S. subsidiaries would result in adverse tax consequences, such pledge shall be limited to 65% of the voting stock and 100% of the non-voting stock of each of our non-U.S. subsidiaries.

The LSA contains customary affirmative and negative covenants, including, without limitation, delivering reports and notices relating to our financial condition and certain regulatory events and intellectual property matters, as well as limiting the creation of liens, the incurrence of indebtedness, and the making of certain investments, payments and acquisitions, other than as specifically permitted by the LSA. The LSA also contains customary events of default (subject, in certain instances, to specified cure periods), including, but not limited to, the failure to make payments of interest or premium when due, the failure to comply with certain covenants and agreements specified in the LSA, and the occurrence of a material adverse change, certain regulatory events, or certain insolvency events. Upon the occurrence of an event of default, the Lenders may declare all outstanding principal and accrued but unpaid interest under the LSA immediately due and payable and may exercise the other rights and remedies as set forth in the LSA.

Equity Distribution Agreement

On August 5, 2019, we entered into an Equity Distribution Agreement (the "Distribution Agreement") with Canaccord Genuity LLC ("Canaccord"), pursuant to which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to $35.0 million. Under the Distribution Agreement, Canaccord may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. We are not obligated to sell any shares under the Distribution Agreement. Canaccord is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement. During the twelve months ended December 31, 2020, we sold 363,120 shares of common stock under the Distribution Agreement at a weighted average price per share of $6.13 resulting in aggregate gross proceeds of $2.2 million. We incurred $67,000 in commissions paid to Canaccord in connection with such sales. As of December 31, 2020, the Company may issue up to an additional $19.7 million of its common stock under the Distribution Agreement.

Biomedical Advanced Research and Development Authority Funding

In March 2020, we were awarded $0.7 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, to develop and pursue FDA EUA of a diagnostic panel that incorporates the new SARS-CoV-2 viral target into our existing ePlex RP Panel. The full $0.7 million was received in September 2020. In June 2020, we submitted our RP2 Panel to the FDA for EUA. In October 2020, our RP2 Panel received EUA from the FDA.

Underwriting Agreement

On May 6, 2020, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Cowen and Company, LLC and William Blair & Company, LLC acting as joint book-running managers and as representatives of the underwriters named therein (collectively, the "Underwriters") relating to the issuance and sale of 7,253,886 shares of common stock and an option, exercisable by the Underwriters for 30 days, to purchase up to an additional 1,088,082 shares of common stock (the "Offering"). The Offering closed on May 11, 2020 and the Company sold 8,341,968 shares of common stock, including the full exercise of the Underwriters' option, at a public offering price of $9.65 per share before underwriting discounts and commissions. The Company raised $75.4 million in net proceeds from the Offering, after deducting underwriters discounts and commissions and offering expenses.

Letter of Credit

The Company has provided an aggregate of $1.6 million in letters of credit to the landlords of certain of its leased facilities and maintains $42,000 in required minimum account balances with the financial institutions issuing such letters of credit. As a result, the Company maintains $1.6 million of restricted cash in connection with these lease agreements as of December 31, 2020.

If we require additional capital, we cannot be certain that it will be available when needed or that our actual cash requirements will not be greater than anticipated. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences, or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as defined in Item 304(a)(4)(ii) of Regulation S-K. The Company has provided $1.6 million in letters of credit to the landlords of certain of its leased facilities, which is recorded as restricted cash on our consolidated balance sheets.

Impact of Inflation

The effect of inflation and changing prices on our operations was not significant during the periods presented.

Contractual Obligations

As of December 31, 2020, we had the following contractual obligations (*in thousands*):

	Payments due by period				
	Less than 1 year	1-3 years	4-5 years	More than 5 years	Total
Operating lease obligations[1]	$ 3,293	$ 6,924	$ 5,168	$ 9,491	$ 24,876
Supplier payment obligations[2]	7,801	8,822	—	—	16,623
Debt obligations[3]	5,969	78,583	—	—	84,552
Other contractual obligations	63	117	88	—	268
Total obligations	$ 17,126	$ 94,446	$ 5,256	$ 9,491	$ 126,319

(1) We enter into leases in the ordinary course of business with respect to our facilities. Our lease agreements have fixed payment terms based on the passage of time. Certain facility leases require payment of maintenance expenses and real estate taxes. Our future operating lease obligations could change if we terminate certain contracts or if we enter into additional leases.

(2) We enter into supplier contracts in the ordinary course of our business. Certain supplier agreements require us to purchase minimum quantities of goods or services on an annual basis.

(3) Our contractual obligations under the LSA consist of principal payments, interest, and fees due to the Lenders.

Critical Accounting Policies and Estimates

Revenue

We recognize revenue from operations through the sale of products and other services. Product revenue comprises the sale of diagnostic tests and instruments. Other revenue primarily consists of freight revenue and revenue from extended service agreements.

Revenue is recognized when control of products and services is transferred to the customer in an amount that reflects the consideration that we expect to receive from the customer in exchange for those products and services. This process involves identifying the contract with the customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once we have transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control.

Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred. Invoicing typically occurs upon shipment and the term between invoicing and when payment is due is not significant. Revenue from instrument services is recognized as the services are rendered, typically evenly over the contract term.

Revenue is recorded net of discounts and sales taxes collected on behalf of governmental authorities. Employee sales commissions are recorded as sales and marketing expense when incurred or amortized over the estimated contract term when resulting from new contract acquisition efforts.

We allocate contract price to each performance obligation in proportion to its stand-alone selling price. The stand-alone selling price is determined by our best estimate of stand-alone selling price using average selling prices over a rolling 12-month period along with a specific assessment of any unique circumstances of the contract. For those products for which there is limited sales history, we make price determinations based on similar product sales data.

Inventory

We value inventories at the lower of cost or net realizable value on a part-by-part basis and provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover, assumptions about future demand for our products, and market conditions. We determine excess and obsolete inventories based on an estimate of the future demand for our products within a specified time horizon, which is generally twelve months. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. If our actual demand is less than our forecast demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Stock-Based Compensation

We generally grant employees and non-employee directors stock-based awards, which typically comprise stock options, restricted stock units, and/or market-based stock units, in connection with their employment or service. We grant stock options with an exercise price equal to the closing price of our common stock on the NASDAQ Global Market on the applicable grant date. We use the Black-Scholes option-pricing model as the method for determining the estimated fair value of stock options, the Monte Carlo Simulation Valuation Model as the method for determining the estimated fair value of our market-based stock units, and we use the grant date fair value of our common stock for valuing restricted stock units. The estimated fair value of stock-based awards exchanged for employee and non-employee director services are expensed over the requisite service period. The stock-based compensation expense related to shares issued under our 2013 Employee Stock Purchase Plan, or ESPP, is also estimated using the Black-Scholes option-pricing model. These models require the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, including the stock award's expected term and the price volatility of the underlying stock. These assumptions include:

- *Expected Term*—expected term represents the period that our stock-based awards are expected to be outstanding and is determined by using the simplified method.
- *Expected Volatility*—expected volatility represents the expected volatility in our stock price over the expected term of the stock option or award.
- *Expected Dividend*—the pricing models require a single expected dividend yield as an input. We assumed no dividends as we have never paid dividends and have no plans to do so.

- *Risk-Free Interest Rate*—the risk-free interest rates used in the models are based on published government rates in effect at the time of grant for periods corresponding with the expected term of the option or award.

Recent Accounting Pronouncements

For a summary of recent accounting pronouncements applicable to our consolidated financial statements, see Note 1, "Summary of Significant Accounting Policies and Significant Accounts" to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of less than three months, and marketable securities, which have maturities between one and twenty-two months. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs, and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may in the future maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and short-term investments, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio. As of December 31, 2020, our marketable securities had a fair market value of $87.6 million, representing 39% of our total assets.

Interest Rate Risk

As of December 31, 2020, based on current interest rates and our total debt outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of GenMark Diagnostics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GenMark Diagnostics, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Revenue recognition – Product revenue sales of consumables and instruments

Description of the Matter:

For the year ended December 31, 2020, sales from product revenue was $169 million. As discussed in Note 1 to the consolidated financial statements, revenue is recognized from product, license, and other revenue. Specifically, product revenue includes the sale of consumables and instruments. The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, when control of the product is transferred to its customers, in an amount that reflects the consideration expected to be received in exchange for the product.

Auditing revenue was especially challenging, specifically product revenue, due to the level of complexity and audit effort required in evaluating the Company's revenue recognition process, including evaluation of the terms and conditions of customer agreements and audit evidence related to product revenue. This includes evaluating each selected agreement for distinct performance obligations as customer agreements can contain unique terms and conditions requiring management to apply judgment in assessing the arrangement.

How We Addressed the Matter in Our Audit

We obtained an understanding of, evaluated the design of and tested the operating effectiveness of controls over the Company's revenue recognition process including sales of product revenue from consumables and instruments.

Our audit procedures included, among others, evaluating the terms and conditions of a sample of customer contracts. We confirmed the terms and conditions with a sample of customers via direct correspondence with the customers. Further, for a sample of individual transactions, we obtained and inspected the executed customer agreements and related audit evidence to test the identification and determination of the distinct performance obligations, and inspected third-party evidence to evaluate when the control of the product was transferred and consideration received in exchange.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2013.
San Diego, California
February 25, 2021

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED BALANCE SHEETS
(*amounts in thousands except par value*)

	December 31,	
	2020	**2019**
ASSETS		
Current assets		
Cash and cash equivalents	$ 40,572	$ 44,360
Short-term marketable securities	87,582	9,100
Accounts receivable, net of allowances of $372 and $376, respectively	20,790	16,759
Inventories, net	21,323	11,301
Prepaid expenses and other current assets	2,695	1,877
Total current assets	172,962	83,397
Property and equipment, net	38,362	20,419
Intangible assets, net	841	1,432
Restricted cash	1,646	758
Operating lease right-of-use assets	8,676	4,642
Other long-term assets	1,047	825
Total assets	$ 223,534	$ 111,473
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 23,071	$ 12,249
Accrued compensation	12,716	7,493
Current operating lease liability	3,093	1,842
Other current liabilities	5,250	2,732
Total current liabilities	44,130	24,316
Long-term debt	71,297	69,145
Noncurrent operating lease liability	12,749	5,796
Other noncurrent liabilities	1,160	53
Total liabilities	129,336	99,310
Stockholders' equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 71,960 and 60,255 shares issued and outstanding at December 31, 2020 and 2019, respectively	7	6
Additional paid-in capital	626,816	526,294
Accumulated deficit	(532,877)	(514,233)
Accumulated other comprehensive income	252	96
Total stockholders' equity	94,198	12,163
Total liabilities and stockholders' equity	$ 223,534	$ 111,473

See accompanying notes to consolidated financial statements.

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(*amounts in thousands except per share data*)

	For the years ended December 31,		
	2020	**2019**	**2018**
Revenue			
Product revenue	$ 169,148	$ 86,821	$ 69,935
Other revenue	2,406	1,200	824
Total revenue	171,554	88,021	70,759
Cost of revenue	103,610	59,418	51,278
Gross profit	67,944	28,603	19,481
Operating expenses			
Sales and marketing	23,164	24,118	21,777
General and administrative	25,572	19,159	17,545
Research and development	30,259	27,140	27,931
Total operating expenses	78,995	70,417	67,253
Operating loss	(11,051)	(41,814)	(47,772)
Other income (expense)			
Interest income	386	512	711
Interest expense	(7,907)	(5,961)	(3,108)
Other income (expense)	9	(23)	(192)
Total other expense	(7,512)	(5,472)	(2,589)
Loss before income taxes	(18,563)	(47,286)	(50,361)
Income tax expense	81	64	139
Net loss	$ (18,644)	$ (47,350)	$ (50,500)
Net loss per share—basic and diluted	$ (0.28)	$ (0.82)	$ (0.91)
Weighted average number of shares outstanding—basic and diluted	67,541	57,603	55,669
Other comprehensive income			
Net loss	$ (18,644)	$ (47,350)	$ (50,500)
Foreign currency translation adjustments, net of tax	147	11	44
Net unrealized gain on marketable securities, net of tax	9	5	27
Total other comprehensive income	156	16	71
Total comprehensive loss	$ (18,488)	$ (47,334)	$ (50,429)

See accompanying notes to consolidated financial statements.

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(*amounts in thousands*)

	Common Stock					
	Shares	Par Value	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
Balance—December 31, 2017	55,066	$ 6	$ 487,525	$ 9	$ (416,383)	$ 71,157
Stock-based compensation expense	—	—	11,697	—	—	11,697
Issuance of employee stock purchase plan shares	253	—	1,061	—	—	1,061
Vesting of restricted stock units	916	—	—	—	—	—
Stock option exercises, net	5	—	21	—	—	21
Reimbursement of offering expenses	—	—	40	—	—	40
Net loss	—	—	—	—	(50,500)	(50,500)
Foreign currency translation adjustments	—	—	—	44	—	44
Unrealized gain on marketable securities	—	—	—	27	—	27
Balance—December 31, 2018	56,240	6	500,344	80	(466,883)	33,547
Stock-based compensation expense	—	—	12,046	—	—	12,046
Issuance of employee stock purchase plan shares	210	—	962	—	—	962
Vesting of restricted stock units	1,461	—	—	—	—	—
Stock option exercises, net	81	—	457	—	—	457
Issuance of common stock, net of offering costs	2,263	—	12,485	—	—	12,485
Net loss	—	—	—	—	(47,350)	(47,350)
Foreign currency translation adjustments	—	—	—	11	—	11
Unrealized gain on marketable securities	—	—	—	5	—	5
Balance—December 31, 2019	60,255	6	526,294	96	(514,233)	12,163
Stock-based compensation expense	—	—	12,796	—	—	12,796
Issuance of employee stock purchase plan shares	171	—	1,068	—	—	1,068
Vesting of restricted stock units	1,686	—	—	—	—	—
Stock option exercises, net	1,143	—	9,068	—	—	9,068
Issuance of common stock, net of offering costs	8,705	1	77,590	—	—	77,591
Net loss	—	—	—	—	(18,644)	(18,644)
Foreign currency translation adjustments	—	—	—	147	—	147
Unrealized gain on marketable securities	—	—	—	9	—	9
Balance—December 31, 2020	71,960	$ 7	$ 626,816	$ 252	$ (532,877)	$ 94,198

See accompanying notes to consolidated financial statements.

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(*amounts in thousands*)

	For the years ended December 31,		
	2020	**2019**	**2018**
Operating activities			
Net loss	$ (18,644)	$ (47,350)	$ (50,500)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	7,066	7,268	7,088
Net amortization (accretion) of premiums/discounts on investments	261	(133)	(142)
Amortization of deferred debt issuance costs	2,253	1,740	938
Stock-based compensation	12,796	12,046	11,697
Provision for bad debt, net of recoveries	17	338	23
Non-cash inventory adjustments	2,319	2,631	1,426
Other non-cash adjustments	360	537	15
Changes in operating assets and liabilities			
Accounts receivable	(4,105)	(5,584)	(878)
Inventories	(12,478)	(6,534)	(2,414)
Prepaid expenses and other assets	(858)	(750)	854
Accounts payable	5,224	1,501	(1,389)
Accrued compensation	4,945	(885)	1,059
Operating lease right-of-use assets and lease liabilities	4,170	—	—
Other current and non-current liabilities	2,808	249	(289)
Net cash provided by (used in) operating activities	6,134	(34,926)	(32,512)
Investing activities			
Purchases of property and equipment	(17,776)	(2,092)	(2,575)
Purchases of marketable securities	(114,186)	(32,135)	(29,778)
Proceeds from sales of marketable securities	1,193	—	—
Maturities of marketable securities	34,260	32,055	66,300
Net cash provided by (used in) investing activities	(96,509)	(2,172)	33,947
Financing activities			
Proceeds from issuance of common stock, net of offering costs	78,659	13,447	1,061
Principal repayment of borrowings	(57)	(35,093)	(92)
Proceeds from borrowings	—	70,000	7,098
Payments associated with debt issuance	(100)	(3,638)	(20)
Proceeds from stock option exercises	9,068	457	22
Net cash provided by financing activities	87,570	45,173	8,069
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(95)	(1)	28
Net increase (decrease) in cash, cash equivalents, and restricted cash	(2,900)	8,074	9,532
Cash, cash equivalents, and restricted cash at beginning of year	45,118	37,044	27,512
Cash, cash equivalents, and restricted cash at end of year	$ 42,218	$ 45,118	$ 37,044
Non-cash investing and financing activities			
Transfer of systems to property and equipment from inventory	$ 137	$ 2,846	$ 1,689
Property and equipment included in accounts payable	$ 6,832	$ 1,234	$ 372
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 4,689	$ —	$ —
Supplemental cash flow information			
Cash paid for interest, net	$ 5,684	$ 3,946	$ 2,028
Cash paid for income taxes, net	$ 91	$ 155	$ 165

See accompanying notes to consolidated financial statements.

1. Nature of Operations and Summary of Significant Accounting Policies

Organization

GenMark Diagnostics, Inc. (the "Company" or "GenMark") is a leading provider of multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. The Company offers a sample-to-answer ePlex instrument and associated molecular diagnostic panels. The Company's products also include the XT-8 instrument and related diagnostic and research tests, as well as certain custom manufactured reagents. The Company sells its products directly to customers in the U.S. and primarily via a network of distribution partners internationally.

Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and applicable regulations of the U.S. Securities and Exchange Commission ("SEC"). These consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

In June 2020, the Company made a policy election to reclassify freight revenue from product revenue to other revenue. The Company reclassified freight revenue of $0.7 million and $0.5 million for the years ended December 31, 2019 and 2018, respectively, from product revenue to other revenue to conform with the current year presentation. The reclassification had no impact to total revenue for the periods presented.

The Company has experienced net losses since its inception and had an accumulated deficit of $532.9 million as of December 31, 2020. The Company's ability to transition to profitable operations is dependent upon achieving a level of revenues adequate to support its cost structure through expanding its product offerings and consequently increasing its product revenues. As of December 31, 2020, the Company had available cash, cash equivalents, and marketable securities of $128.2 million and working capital of $128.8 million available to fund future operations. The Company has prepared cash flow forecasts which indicate, based on the Company's current cash resources available and working capital, that the Company will have sufficient resources to fund its operations for at least one year after the date the financial statements are issued.

Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes thereto. The Company's significant estimates included in the preparation of the financial statements are related to accounts receivable, inventories, property and equipment, leases, intangible assets, employee-related compensation accruals, warranty liabilities, tax valuation accounts, and stock-based compensation. Actual results could differ from those estimates.

Segment Information

The Company currently operates in one reportable business segment, which encompasses the development, manufacturing, sales and support of instruments and molecular tests based on its proprietary eSensor® detection technology. Substantially all of the Company's operations and assets are in the United States.

Revenue

The Company recognizes revenue from operations through the sale of products and other services. Product revenue comprises the sale of diagnostic tests and instruments. Other revenue primarily consists of freight revenue and revenue from extended service agreements.

Revenue is recognized when control of products and services is transferred to the customer in an amount that reflects the consideration that the Company expects to receive from the customer in exchange for those products and services. This process involves identifying the contract with the customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred. Invoicing typically occurs upon shipment and the term between invoicing and when payment is due is not significant. Revenue from instrument services is recognized as the services are rendered, typically evenly over the contract term.

Revenue is recorded net of discounts and sales taxes collected on behalf of governmental authorities. Employee sales commissions are recorded as sales and marketing expense when incurred or amortized over the estimated contract term when resulting from new contract acquisition efforts.

The Company allocates contract price to each performance obligation in proportion to its stand-alone selling price. The stand-alone selling price is determined by the Company's best estimate of stand-alone selling price using average selling prices over a rolling 12-month period along with a specific assessment of any unique circumstances of the contract. For those products for which there is limited sales history, the Company makes price determinations based on similar product sales data.

The following table represents disaggregated revenue by source (*in thousands*):

	For the years ended December 31,		
	2020	2019	2018
Revenue Source			
ePlex product revenue	$ 152,578	$ 59,799	$ 37,601
XT-8 product revenue	16,570	27,022	32,334
Total product revenue	169,148	86,821	69,935
License and other revenue	2,406	1,200	824
Total revenue	$ 171,554	$ 88,021	$ 70,759

Cash, Cash Equivalents, and Marketable Securities

Cash and cash equivalents consist of cash on deposit with banks, money market instruments, and certificates of deposit with original maturities of three months or less at the date of purchase. The Company classifies marketable securities as available-for-sale at the time of purchase and reevaluates such classification as of each balance sheet date. All marketable securities are recorded at estimated fair value. Unrealized gains and losses for available-for-sale securities are included in accumulated other comprehensive income, a component of stockholders' equity. The Company evaluates its marketable securities to assess whether those with unrealized loss positions are other-than-temporarily impaired. Impairments are considered to be other-than-temporary if they are related to deterioration in credit risk or if it is likely that the Company will sell the securities before the recovery of its cost basis. Realized gains and losses and declines in value judged to be other-than-temporary are determined based on the specific identification method and are reported in other income (expense) in the consolidated statements of comprehensive loss.

The Company has the ability, if necessary, to liquidate any of its short-term debt securities to meet liquidity needs in the next 12 months. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as short-term investments on the consolidated balance sheets.

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and was $1.6 million and $0.8 million at December 31, 2020 and 2019, respectively, which represented an amount held as security for the Company's facility lease agreements.

The following table shows a reconciliation of the Company's cash and cash equivalents in the consolidated balance sheet to cash, cash equivalents, and restricted cash in the consolidated statement of cash flows as of December 31, 2020 and 2019 (*in thousands*):

	December 31,	
	2020	2019
Cash and cash equivalents	$ 40,572	$ 44,360
Restricted cash	1,646	758
Total cash, cash equivalents, and restricted cash	$ 42,218	$ 45,118

Fair Value of Financial Instruments

The Company uses a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value:

- *Level 1*—Quoted prices in active markets for identical assets or liabilities.
- *Level 2*—Inputs, other than Level 1, that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3*—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of financial instruments such as accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued liabilities approximate the related fair values due to the short-term maturities of these instruments.

Receivables

Accounts receivable consists of amounts due to the Company from the sale of products and services to customers. Accounts receivable is recognized at amortized cost and is recorded net of an allowance for credit losses. The Company views its accounts receivable as a single portfolio and considers the period of delinquency, historical collection rates, and customer specific-factors in determining its allowance for credit losses.

The following table summarizes the composition of the allowance for credit losses (*in thousands*):

	For the years ended December 31,		
	2020	2019	2018
Beginning balance	$ 376	$ 75	$ 2,754
Provision for credit losses, net	17	338	23
Write off of uncollectible accounts	(21)	(37)	(2,702)
Ending balance	$ 372	$ 376	$ 75

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value and include direct labor, materials, and manufacturing overhead. The Company periodically reviews inventory for evidence of slow-moving or obsolete parts, and writes inventory down to net realizable value, as needed. This write-down is based on management's review of inventories on hand, compared to estimated future usage and sales, shelf-life assumptions, and assumptions about the likelihood of obsolescence. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable.

Product Warranties

The Company generally offers a one-year warranty for instruments and a 60-day warranty for consumables sold to customers. Factors that affect the Company's warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs, and the cost per repair. The Company periodically assesses the adequacy of its warranty reserve and adjusts the amount as appropriate.

The following table summarizes warranty reserve activity (*in thousands*):

	For the years ended December 31,		
	2020	2019	2018
Beginning balance	$ 279	$ 330	$ 470
Provision	1,508	1,275	1,355
Warranty expenses incurred	(1,551)	(1,326)	(1,495)
Ending balance	$ 236	$ 279	$ 330

Property and Equipment, net

Property, equipment, and leasehold improvements are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which are identified below. Repair and maintenance costs are expensed as incurred.

Machinery and laboratory equipment	3 - 5 years
Instruments	4 - 7 years
Office equipment	3 - 7 years
Leasehold improvements	Over the shorter of the remaining life of the lease or the useful economic life of the asset

Property and equipment includes diagnostic instruments used for sales demonstrations or placed with customers under several types of arrangements, including performance evaluation programs ("PEPs") and reagent rental agreements. Instruments are placed with customers under PEPs for limited evaluation periods. Instruments are also placed with customers under reagent rental agreements, which generally require customers to purchase a minimum number of test cartridges over the term of the agreement. The Company retains title to the instrument under these arrangements. Maintenance and repair costs are expensed as incurred.

Leased property meeting certain finance lease criteria is capitalized, and the net present value of the related lease payments is recorded as a liability. Amortization for assets noted as finance leases is recorded using the straight-line method over the shorter of the estimated useful lives or the lease terms.

Intangible Assets

Intangible assets consist of licenses or sublicenses to technology covered by patents owned by third parties, and are amortized on a straight-line basis over the expected useful lives of these assets, which is generally ten years. Amortization of licenses typically begins upon the Company obtaining access to the licensed technology and is recorded in cost of revenues for licenses supporting commercialized products. The amortization of licenses to technology supporting products in development is recorded in research and development expense.

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, including intangible assets, by periodically evaluating the carrying value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If impairment is indicated, the Company writes down the carrying value of the asset to its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows. The Company did not recognize any impairment of long-lived asset charges during the years ended December 31, 2020, 2019, and 2018.

Other current liabilities

The following table summarizes the composition of current liabilities (*in thousands*):

	December 31,	
	2020	2019
Accrued royalties	$ 1,863	$ 882
Deferred revenue	508	323
Accrued interest	507	437
Accrued warranties	236	279
Other accrued liabilities	2,136	811
Total other current liabilities	$ 5,250	$ 2,732

Employee Benefit Plan

The Company has a 401(k) tax-deferred savings plan, whereby eligible employees may contribute a percentage of their eligible compensation. The Company makes matching contributions under the 401(k) plan to certain eligible employees.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are recorded in the consolidated balance sheets as operating lease right-of-use ("ROU") assets and current and noncurrent operating lease liabilities. Finance leases are recorded in the consolidated balance sheets as other noncurrent assets and other current and noncurrent liabilities.

ROU assets represent the Company's right to use an underlying asset over the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at the commencement date based on the present value of the Company's lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of its lease payments. ROU assets are recognized at the commencement date based upon the initial measurement of the operating lease liability less any lease incentives received.

The Company's lease agreements can include both lease and non-lease components. The Company accounts for each lease component separately from the non-lease components within its lease agreements.

Research and Development Costs

The Company expenses all research and development costs in the periods in which they are incurred unless there is alternative future use that supports the capitalization of an asset.

Stock-Based Compensation

The Company recognizes stock-based compensation expense related to stock options, restricted stock units, market-based stock units, and shares purchased under the Company's Amended and Restated 2013 Employee Stock Purchase Plan ("ESPP") granted to employees, non-employees, and directors in exchange for services. The compensation expense is based on the fair value of the applicable award utilizing various assumptions regarding the underlying attributes of the award. The stock-based compensation expense is recorded in cost of revenues, sales and marketing, research and development, and/or general and administrative expenses based on the employee's respective function.

The estimated fair value of stock granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense that approximates straight-line expense to reflect vesting as it occurs. The compensation expense related to the grant of restricted stock awards or units is calculated as the fair market value of the stock on the grant date as further adjusted to reflect expected forfeitures. The stock option expense is derived from the Black-Scholes option pricing model that uses several judgment-based variables to calculate the expense. The market-based stock expense is derived from the Monte Carlo Simulation Valuation. The inputs utilized in the valuation of the stock-based awards include the following factors:

- *Expected Term*—Expected term represents the period that the stock-based awards are expected to be outstanding and is determined by using the simplified method.
- *Expected Volatility*—Expected volatility represents the expected volatility in the Company's stock price over the expected term of the option or market-based award and is determined by review of the Company's and similar companies' historical experience.
- *Expected Dividend*—The valuation methods requires a single expected dividend yield as an input. The Company assumed no dividends as it has never paid dividends and has no current plans to do so.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on published U.S. Treasury rates in effect at the time of grant for periods corresponding with the expected term of the option or market-based award.

Foreign Currency Translation

The Company translates the assets and liabilities of the Company's entities outside the U.S. into U.S. Dollars based on the foreign currency exchange rates at the end of each period. Gains or losses resulting from these foreign currency translations are recorded in accumulated other comprehensive income in the consolidated statement of stockholders' equity. Foreign currency translation impacts recorded in accumulated other comprehensive income for the years ended December 31, 2020, 2019, and 2018 were $147,000, $11,000, and $44,000, respectively.

Income Taxes

Current income tax expense is the amount of income taxes expected to be payable for the current year. A deferred income tax liability or asset is established for the expected future tax consequences resulting from the differences in financial reporting and tax bases of assets and liabilities. A valuation allowance is provided if it is more likely than not that some or all of the deferred tax assets will not be realized. A full valuation allowance has been recorded against the Company's net deferred tax assets due to the uncertainty surrounding the Company's ability to utilize these assets in the future. The Company provides for uncertain tax positions when such tax positions do not meet the recognition thresholds or measurement standards prescribed by the authoritative guidance on income taxes. Amounts for uncertain tax positions are adjusted in periods when new information becomes available or when positions are effectively settled. The Company recognizes accrued interest related to uncertain tax positions as a component of income tax expense.

A tax position that is more likely than not to be realized is measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with the taxing authority that has full knowledge of all relevant information. Measurement of a tax position that meets the more likely than not threshold considers the amounts and probabilities of the outcomes that could be realized upon settlement using the facts, circumstances and information available at the reporting date.

Net Loss Per Common Share

Basic net loss per share is calculated by dividing loss available to stockholders of the Company's common stock (the numerator) by the weighted average number of shares of the Company's common stock outstanding during the period (the denominator). Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted loss per share is calculated in a similar way to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the dilutive potential shares had been issued, unless the effect would be anti-dilutive.

The calculations of diluted net loss per share for the years ended December 31, 2020, 2019, and 2018 did not include the effects of the following stock options and other equity awards which were outstanding as of the end of each period because the inclusion of these securities would have been anti-dilutive (*in thousands*):

	For the years ended December 31,		
	2020	2019	2018
Options outstanding to purchase common stock	843	2,037	2,440
Other unvested equity awards	3,173	3,124	2,994
Total	4,016	5,161	5,434

Concentration of Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investment securities, and accounts receivable. The Company limits its exposure to credit loss by placing its cash with high credit quality financial institutions. The Company has established guidelines to diversify its cash and investment securities and their maturities that are intended to secure safety and liquidity.

For the years ended December 31, 2020, 2019, and 2018, revenue from one customer represented 10%, 14%, and 16%, respectively, of the Company's total revenue. As of December 31, 2020, no customers accounted for more than 10% of net accounts receivable. As of December 31, 2019, two customers accounted for more than 10% of net accounts receivable, with such customers accounting for 24% and 11% of net accounts receivable.

Comprehensive Loss

The Company has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The Company's comprehensive loss comprises net loss, unrealized gains and losses on available for sale securities, and foreign currency translation.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, which introduced a new methodology for recognizing credit losses on financial instruments. The new standard requires entities to measure financial instruments at their amortized cost basis, net of an allowance for credit losses. The allowance for credit losses must reflect an entity's current estimate of all expected credit losses. The new guidance also requires entities to present credit losses on debt securities accounted for under the available-for-sale method as an allowance rather than a write-down. The Company adopted the new standard in the first quarter of 2020. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements for the year ended December 31, 2020.

2. Inventories

The following table summarizes the composition of inventory on hand as of December 31, 2020 and 2019 (*in thousands*):

	December 31,	
	2020	2019
Raw materials	$ 10,087	$ 3,408
Work-in-process	7,958	3,776
Finished goods	3,278	4,117
Total inventories	$ 21,323	$ 11,301

3. Intangible Assets, Net

The following table summarizes the composition of intangible assets as of December 31, 2020 and 2019 (*in thousands*):

	December 31, 2020			December 31, 2019		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Licensed intellectual property	$ 4,750	$ (3,909)	$ 841	$ 4,750	$ (3,318)	$ 1,432

Intellectual property licenses have a weighted average remaining amortization period of 1.4 years as of December 31, 2020. Amortization expense for these licenses was $0.6 million during both the years ended December 31, 2020 and 2019.

Estimated future amortization expense for these licenses is as follows (*in thousands*):

Fiscal Years Ending	Future Amortization Expense
2021	$ 591
2022	250
Total	$ 841

4. Property and Equipment, Net

The following table summarizes the composition of property and equipment as of December 31, 2020 and 2019 (*in thousands*)

	December 31, 2020	December 31, 2019
Property and equipment—at cost:		
Machinery and laboratory equipment	$ 22,367	$ 16,551
Instruments	13,686	16,796
Office equipment	2,402	2,150
Leasehold improvements	29,280	11,896
Total property and equipment—at cost	67,735	47,393
Less: accumulated depreciation	(29,373)	(26,974)
Property and equipment, net	$ 38,362	$ 20,419

Depreciation expense was $5.5 million, $5.9 million, and $5.9 million for the years ended December 31, 2020, 2019, and 2018, respectively. During the years ended December 31, 2020, 2019, and 2018, the Company disposed of certain assets no longer in use with a net book value of approximately $0.5 million in each year, recorded to cost of revenue, sales and marketing, research and development, or general and administrative expenses based on the asset's respective use.

5. Marketable Securities

The following table summarizes the Company's marketable securities as of December 31, 2020 and 2019 (*in thousands*):

December 31, 2020	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds, short-term	$ 22,294	$ 2	$ (2)	$ 22,294
U.S. government and agency securities, short-term	14,496	5	—	14,501
International bonds, short-term	4,003	—	(1)	4,002
Commercial paper, short-term	46,777	8	—	46,785
Total	$ 87,570	$ 15	$ (3)	$ 87,582

December 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds, short-term	$ 9,099	$ 2	$ (1)	$ 9,100
Total	$ 9,099	$ 2	$ (1)	$ 9,100

6. Fair Value of Financial Instruments

The following table presents the financial instruments measured at fair value on a recurring basis and the valuation approach applied to each class of financial instruments as of December 31, 2020 and 2019 (*in thousands*):

	December 31, 2020			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents				
Money market funds	$ 20,077	$ —	$ —	$ 20,077
Marketable securities				
Corporate notes and bonds	—	22,294	—	22,294
U.S. government and agency securities	—	14,501	—	14,501
International bonds	—	4,002	—	4,002
Commercial paper	—	46,785	—	46,785
Total short-term assets at fair value	20,077	87,582	—	107,659
Long-term marketable securities				
U.S. government and agency securities	—	—	—	—
Total assets at fair value	$ 20,077	$ 87,582	$ —	$ 107,659

	December 31, 2019			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents				
Money market funds	$ 19,647	$ —	$ —	$ 19,647
Marketable securities				
Corporate notes and bonds	—	9,100	—	9,100
Total assets at fair value	$ 19,647	$ 9,100	$ —	$ 28,747

Level 2 marketable securities are priced using quoted market prices for similar instruments or nonbinding market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs.

7. Long-Term Debt

Term Loans

As of December 31, 2020 and 2019, long-term debt consisted of the following (*in thousands*):

	December 31, 2020	December 31, 2019
Term Loan	70,000	70,000
Final fee obligation	4,865	4,165
Unamortized issuance costs	(3,568)	(5,020)
Total debt, net	71,297	69,145
Current portion of long-term debt	—	—
Long-term debt	$ 71,297	$ 69,145

On February 1, 2019 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "LSA"), with Solar Capital Ltd. and certain other financial institutions (collectively, the "Lenders"). Pursuant to the LSA, the Lenders have provided the Company with a total of $70.0 million in a series of term loans (collectively, the "Term Loans"), of which $50.0 million was funded on the Effective Date, and an additional $20.0 million was funded in December 2019 upon the Company's achievement of a designated amount of product revenues on a trailing six-month basis.

The Term Loans under the LSA accrue interest at a floating per annum rate in effect from time-to-time equal to (a) the greater of 2.51% or the one-month Intercontinental Exchange Benchmark Administration, Ltd. rate then in effect as of the applicable payment date, plus (b) 5.90% per annum. The Company is only required to make interest payments on amounts borrowed pursuant to the Term Loans from the applicable funding date until February 28, 2022 (the "Interest Only Period"). Following the Interest Only Period, monthly installments of principal and interest under the Term Loans will be due until the original principal amount and applicable interest is fully repaid by February 1, 2023. Due to the floating per annum rate, the fair value approximates the carrying value of our outstanding Term Loans.

Under the LSA, the Company is required to comply with certain affirmative and negative covenants, including, without limitation, delivering reports and notices relating to the Company's financial condition and certain regulatory events and intellectual property matters, as well as limiting the creation of liens, the incurrence of indebtedness, and the making of certain investments, dividends, payments and acquisitions, other than as specifically permitted by the LSA. As of December 31, 2020, the Company was in compliance with all covenants under the LSA.

The LSA also contains customary events of default (subject, in certain instances, to specified cure periods), including, but not limited to, the failure to make payments of interest or premium when due, the failure to comply with certain covenants and agreements specified in the LSA, and the occurrence of a material adverse change, certain regulatory events, or certain insolvency events. Upon the occurrence of an event of default, the Lenders may declare all outstanding principal and accrued but unpaid interest under the LSA immediately due and payable and may exercise the other rights and remedies as set forth in the LSA.

Debt Issuance Costs

As of December 31, 2020 and 2019, the Company had $3.6 million and $5.0 million, respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt. Amortization of debt issuance costs was $2.3 million, $1.7 million, and $0.9 million for the years ended December 31, 2020, 2019, and 2018, respectively. Amortization of debt issuance costs is included in interest expense in the Company's consolidated statements of comprehensive loss for the periods presented.

Letter of Credit

The Company has provided an aggregate of $1.6 million in letters of credit to the landlords of certain of its leased facilities and maintains $42,000 in required minimum account balances with the financial institutions issuing such letters of credit. As a result, the Company maintains $1.6 million of restricted cash in connection with these lease agreements as of December 31, 2020.

8. Commitments and Contingencies

Leases

On July 2, 2020, the Company entered into a Single Tenant Industrial Triple Net Lease (the "Lease"), with Icon Owner Pool 1 West/Southwest, LLC, as landlord (the "Landlord"). Pursuant to the Lease, the Company has leased an approximately 73,000 square foot facility in Carlsbad, California (the "Facility"), which the Company may use for manufacturing, research and development, office, and/or distribution purposes. The original term of the Lease runs through June 30, 2031. In addition, subject to the terms and conditions of the Lease, the Landlord has granted the Company an ongoing right of first refusal to lease two additional buildings located adjacent to the Facility. Under the Lease, the Company will pay the Landlord base rent commencing on February 1, 2021 of approximately $0.1 million per month, which base rent amount will increase annually at a rate of 3%. The base rent amount payable

by the Company is in addition to “triple net” operating expenses payable by the Company, as set forth in the Lease. In addition, the Company has provided the Landlord a standby letter of credit in the amount of approximately $0.8 million as security for the Company’s full performance of its obligations under the Lease. In connection with entering into the Lease, and subject to the terms and conditions set forth therein, the Landlord has agreed to provide the Company a tenant improvement allowance for the Facility in an amount up to $4.2 million.

The Company has operating lease agreements for its office, manufacturing, warehousing and laboratory space. Rent and operating expenses charged under these arrangements was $2.5 million, $2.0 million, and $1.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

The Company reported noncurrent operating lease ROU assets of $8.7 million and $4.6 million, current operating lease liabilities of $3.1 million and $1.8 million, and noncurrent operating lease liabilities of $12.7 million and $5.8 million, respectively, as of December 31, 2020 and 2019. The Company’s operating lease liabilities were measured at a weighted average discount rate of 11.4% and have a weighted average remaining term of 7.9 years.

Maturities of our operating lease liabilities as of December 31, 2020 are as follows (*in thousands*):

Fiscal Years Ending	Operating Leases
2021	$ 3,293
2022	3,509
2023	3,415
2024	2,902
2025	2,266
Thereafter	9,491
Total	24,876
Less: imputed interest	(9,034)
Total operating lease liabilities	$ 15,842

Legal Proceedings

From time to time, the Company is party to litigation and other legal proceedings in the ordinary course, and incidental to the conduct of its business. While the results of any litigation or other legal proceedings are uncertain, the Company does not believe the ultimate resolution of any pending legal matters is likely to have a material effect on its financial position or results of operations.

9. Stockholders’ Equity

On May 6, 2020, the Company entered into an Underwriting Agreement (the “Underwriting Agreement”), with Cowen and Company, LLC and William Blair & Company, LLC acting as joint book-running managers and as representatives of the underwriters named therein (collectively the “Underwriters”) relating to the issuance and sale of 7,253,886 shares of the Company’s common stock (the “Offering”). Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 1,088,082 shares of common stock. The Offering closed on May 11, 2020 and the Company sold 8,341,968 shares of common stock, including the full exercise of the Underwriters' option, at a public offering price of $9.65 per share before underwriting discounts and commissions. The Company raised $80.5 million in gross proceeds from the Offering and incurred $4.8 million in Underwriters’ discounts and commissions and $0.2 million in professional services related to the Offering.

On August 5, 2019, the Company entered into an Equity Distribution Agreement (the “Distribution Agreement”) with Canaccord Genuity LLC (“Canaccord”), pursuant to which the Company may offer and sell, from time to time, shares of the Company’s common stock having an aggregate offering price of up to $35.0 million. Under the Distribution Agreement, Canaccord may sell shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. The Company is not obligated to sell any shares under the Distribution Agreement. Canaccord is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement. During the year ended December 31, 2020, the Company sold 363,120 shares of common stock under the Equity Distribution Agreement at a weighted average price per share of $6.13 resulting in aggregate gross proceeds of $2.2 million. The Company incurred $67,000 in commissions paid to Canaccord in connection with such sales. As of December 31, 2020, the Company may issue up to an additional $19.7 million of its common stock under the Distribution Agreement.

10. Stock-Based Compensation

Equity awards may be granted at the discretion of the Compensation Committee of the Board of Directors under the Company's equity plans, in connection with the hiring or retention of personnel and are subject to certain conditions. In May 2020, the Company’s stockholders approved the Company’s 2020 Equity Incentive Plan (“2020 Plan”). Prior to the adoption of the 2020 Plan, the Company

granted equity awards under its 2010 Equity Incentive Plan, as amended ("2010 Plan"), which expired in May 2020. The Company recognizes stock-based compensation expense related to stock options, restricted stock units, and market-based stock units granted to employees, directors, and non-employee advisors in exchange for services under the 2020 Plan and 2010 Plan (together the "Equity Plans") and employee stock purchases under the ESPP. Employee participation in the Equity Plans is at the discretion of the Compensation Committee of the Board of Directors of the Company. Each equity award reduces the number of shares available for grant under the applicable Equity Plan. Stock-based compensation expense is recorded in cost of sales, sales and marketing, research and development, and general and administrative expense based on employees' respective function. During the years ended December 31, 2020, 2019, and 2018 the Company recognized stock-based compensation expense of $12.8 million, $12.0 million, and $11.7 million, respectively. As of December 31, 2020, there were 4,569,567 shares available for future grant of awards under the 2020 Plan.

Stock Options

All stock options granted under the Equity Plans are exercisable at a per share price equal to the closing quoted market price of a share of the Company's common stock on the NASDAQ stock market on the grant date and generally vest over a period of four years. Stock options are generally exercisable for a period of up to ten years after grant and are typically forfeited if employment is terminated before the options vest.

The Company's stock option activity for the year ended December 31, 2020 was as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2019	2,037,132	$ 9.53
Exercised	(1,178,431)	$ 8.08
Cancelled	(15,444)	$ 12.07
Outstanding at December 31, 2020	843,257	$ 11.50
Vested and expected to vest at December 31, 2020	843,257	$ 11.50
Exercisable at December 31, 2020	843,257	$ 11.50

There were 843,257 stock options exercisable and outstanding as of December 31, 2020, all of which were granted under the 2010 Plan and which had a remaining weighted average contractual term of 3.4 years and an aggregate intrinsic value of $2.6 million. The Company has recognized all compensation expense related to stock options granted under the 2010 Plan. The Company did not grant any stock options under the 2020 Plan during the year ended December 31, 2020. The intrinsic value of stock options exercised during the years ended December 31, 2020, 2019, and 2018 was $4.8 million, $0.1 million, and $7,000, respectively.

Restricted Stock Units

Restricted stock units granted under the Equity Plans generally vest over a period of between one and four years and are typically forfeited if service to the Company ceases before the restricted stock units vest. The compensation expense related to the restricted stock units is calculated as the fair market value of the Company's stock on the grant date and is adjusted for estimated forfeitures. Restrictions expire after the grant date in accordance with specific provisions in the applicable award agreement.

The Company's restricted stock unit activity for the year ended December 31, 2020 was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2019	2,669,499	$ 6.42
Granted	2,022,136	$ 4.73
Vested	(1,512,729)	$ 6.48
Cancelled	(477,941)	$ 5.75
Outstanding at December 31, 2020	2,700,965	$ 5.24

As of December 31, 2020, there was $10.6 million of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.0 years. The total fair value of restricted stock units that vested during the years ended December 31, 2020, 2019, and 2018 was $15.1 million, $8.7 million, and $5.4 million, respectively.

Market-Based Stock Units

The Company granted market-based stock units in each of February 2020, 2019, and 2018, which may result in the recipient receiving shares of stock equal up to 200% of the target number of units granted. The vesting and issuance of Company stock pursuant to market-based stock units depends on the Company's stock performance as compared to the NASDAQ Composite Index over the three-year period following the grant, subject to the recipient's continued service with the Company. As of December 31, 2020, there

was $0.9 million of unrecognized stock-based compensation expense related to market-based stock unit awards, which is expected to be recognized over a weighted average period of 1.5 years. The total fair value of market-based stock units that vested during the years ended December 31, 2020, 2019, and 2018 was $1.0 million, $0.8 million, and $0.6 million, respectively.

The Company's market-based stock unit activity for the year ended December 31, 2020 was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2019	454,229	$ 9.40
Granted	321,250	$ 4.39
Vested	(189,167)	$ 9.32
Cancelled	(114,466)	$ 8.53
Outstanding at December 31, 2020	471,846	$ 6.32

The fair value of these market-based stock units was estimated on the grant date using the Monte Carlo Simulation Valuation Model, which estimates the potential outcome of achieving the market conditions based on simulated future stock prices, with the following assumptions for the years ended December 31, 2020, 2019, and 2018:

	Years Ended December 31,		
	2020	2019	2018
Expected volatility	62 %	64 %	65 %
Risk-free interest rate	1.16 %	2.50 %	2.40 %
Expected dividend	— %	— %	— %
Weighted average fair value	$ 4.39	$ 10.22	$ 7.19

Employee Stock Purchase Plan

The Company's stockholders originally approved the ESPP in May 2013. In May 2018, the Company's stockholders approved the amendment and restatement of the ESPP, which increased the shares authorized for issuance under the ESPP from 650,000 shares to 1,750,000 shares.

The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors; provided that no offering period may exceed 27 months. Employees may invest up to 10% of their qualifying gross compensation through payroll deductions. In no event may an employee purchase more than 1,500 shares of common stock during any six-month offering period. As of December 31, 2020, there were 559,336 shares of common stock available for issuance under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation; therefore, stock-based compensation expense related to the ESPP has been recorded in each of the periods presented.

The following table summarizes ESPP activity for the years ended December 31, 2020, 2019, and 2018 (*in thousands, except share and per share data*):

	Years Ended December 31,		
	2020	2019	2018
Shares issued	171,580	209,577	252,623
Weighted average fair value of shares issued	$ 6.23	$ 4.59	$ 4.20
Employee purchases	$ 1,068	$ 962	$ 1,061

The Company uses the Black-Scholes model to estimate the fair value on the grant date for ESPP purchase rights. The following table summarizes the assumptions used in the valuation for the years ended December 31, 2020, 2019, and 2018:

	Years Ended December 31,		
	2020	2019	2018
Expected volatility	77.6% - 122.1%	40.0% - 50.0%	54.0% - 73.0%
Expected life	6 months	6 months	6 months
Risk free rate	0.1% - 0.2%	1.6% - 2.3%	2.1% - 2.6%
Expected dividend yield	—%	—%	—%

Stock-Based Compensation Expense Recognition

Stock-based compensation was recognized in the consolidated statements of comprehensive loss as follows (*in thousands*):

	Years Ended December 31,		
	2020	2019	2018
Cost of revenue	830	953	871
Sales and marketing	2,610	3,014	5,549
General and administrative	7,190	6,335	2,807
Research and development	2,166	1,744	2,470
Total stock-based compensation expense	$ 12,796	$ 12,046	$ 11,697

The Company did not capitalize stock-based compensation expense during the periods presented and there was no unrecognized tax benefit related to stock-based compensation for any of the years ended December 31, 2020, 2019, or 2018.

11. Income Taxes

The Company's loss before provision for income taxes for the years ended December 31, 2020, 2019, and 2018, respectively, was generated in the following jurisdictions (*in thousands*):

	Years Ended December 31,		
	2020	2019	2018
Domestic	$ (19,045)	$ (47,807)	$ (50,938)
Foreign	482	521	577
Total loss before income taxes	$ (18,563)	$ (47,286)	$ (50,361)

The components of income tax expense were as follows for the years ended December 31, 2020, 2019, and 2018, respectively (*in thousands*):

	Years Ended December 31,		
	2020	2019	2018
Current expense			
U.S. Federal	$ —	$ 27	$ 4
State	16	29	43
Foreign	67	11	99
Total current expense	83	67	146
Deferred benefit			
U.S. Federal	(2)	(2)	(5)
State	—	(1)	(2)
Total deferred benefit	(2)	(3)	(7)
Provision for income taxes	$ 81	$ 64	$ 139

The components of net deferred income taxes consisted of the following at December 31, 2020 and 2019, respectively (*in thousands*):

	December 31,	
	2020	2019
Deferred income tax assets:		
NOL and credit carryforwards	$ 83,903	$ 84,362
Compensation accruals	4,589	4,669
Accruals and reserves	1,523	764
Operating lease liability	3,746	1,906
State tax provision	4	6
Inventory adjustments	1,722	881
Intangible assets	710	542
Other	2,386	2,031
Gross deferred tax assets	98,583	95,161
Less: valuation allowance	(95,495)	(92,717)
Total deferred tax assets	3,088	2,444
Deferred income tax liabilities:		
Depreciation	677	951
Contract acquisition costs	359	334
Operating lease right-of-use assets	2,052	1,159
Total deferred tax liabilities	3,088	2,444
Net deferred tax assets (liabilities)	$ —	$ —

A reconciliation of income tax expense to the amount computed by applying the statutory federal income tax rate to the loss from operations is summarized for the years ended December 31, 2020, 2019, and 2018, respectively, as follows:

	Years Ended December 31,		
	2020	2019	2018
U.S. Federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Permanent differences	(0.8)%	(0.3)%	(0.2)%
State taxes	1.7 %	3.8 %	3.0 %
Executive compensation limitation	(8.8)%	(0.9)%	(0.5)%
Tax reform	— %	— %	0.1 %
Stock-based compensation	3.9 %	(1.2)%	(2.6)%
Rate adjustment	(3.1)%	— %	— %
Other	0.5 %	0.1 %	0.1 %
Valuation allowance	(14.9)%	(22.7)%	(21.2)%
Total tax provision	(0.5)%	(0.2)%	(0.3)%

The Company had pre-2018 federal net operating loss (“NOL”) carryforwards available of approximately $264.0 million as of December 31, 2020 after consideration of limitations under Section 382 of the Internal Revenue Code (“Section 382”), as further described below. The federal NOL carryforwards generated prior to 2018 will begin to expire in 2025. The NOLs generated in 2018 and 2019 of approximately $77.8 million will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. Additionally, the Company had state NOL carryforwards available of approximately $243.7 million as of December 31, 2020. The state NOLs may be used to offset future taxable income and have begun to expire.

The future utilization of the Company’s NOL carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of changes in ownership by stockholders that hold 5.0% or more of the Company’s common stock. An assessment of such ownership changes under Section 382 was completed through December 31, 2020. As a result of this assessment, the Company determined that it experienced multiple ownership changes through 2020 which will limit the future utilization of NOL carryforwards. The Company has reduced its deferred tax assets related to NOL carryovers that are anticipated to expire unused as a result of ownership changes. These tax attributes have been excluded from deferred tax assets with a corresponding reduction of the

valuation allowance with no net effect on income tax expense or the effective tax rate. Additionally, future ownership changes may further impact the utilization of existing NOLs.

The Company has established a full valuation allowance for its deferred tax assets due to uncertainties that preclude it from determining that it is more likely than not that the Company will be able to generate sufficient taxable income to realize such assets. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three year period ended December 31, 2020. Such objective evidence limits the ability to consider other subjective evidence, such as the Company's projections for future growth. Based on this evaluation, as of December 31, 2020, a valuation allowance of $95.5 million has been recorded in order to measure only the portion of the deferred tax asset that more likely than not will be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence, such as estimates of future taxable income during carryforward periods and the Company's projections for growth.

The Company applies the two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount, which is more than 50.0% likely of being realized upon ultimate settlement. Income tax positions must meet a more likely than not recognition threshold at the effective date to be recognized upon the adoption of ASC 740 and in subsequent periods. This interpretation also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. There were no unrecognized tax benefits for the years ended December 31, 2020, 2019, or 2018.

At December 31, 2020 and 2019, the Company had not accrued any interest or penalties related to uncertain tax positions. The Company does not anticipate that there will be a significant change in the amount of unrecognized tax benefits over the next twelve months. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

The Company is subject to taxation in the United States and various state and foreign jurisdictions. The Company's Federal and state tax returns since inception are subject to examination due to the carryover of net operating losses. As of December 31, 2020, the Company's 2014 fiscal year tax return is subject to examination by the United Kingdom tax authorities. The statute of limitations for the assessment and collection of income taxes related to other foreign tax returns varies by country. In the foreign countries where the Company has operations, these time periods generally range from three to six years after the year for which the tax return is due or the tax is assessed.

12. Quarterly Financial Data (Unaudited)

The following table sets forth selected quarterly financial data for the years ended December 31, 2020, 2019, and 2018 (*in thousands except per share data*):

	2020			
	First Quarter	**Second Quarter**	**Third Quarter**	**Fourth Quarter**
Total revenue	$ 38,742	$ 40,086	$ 42,646	$ 50,080
Gross profit	$ 16,152	$ 15,851	$ 16,543	$ 19,398
Loss from operations	$ (5,005)	$ (2,693)	$ (1,266)	$ (2,087)
Net loss	$ (7,008)	$ (4,684)	$ (3,228)	$ (3,724)
Net loss per share:				
Net loss per share—basic and diluted	$ (0.12)	$ (0.07)	$ (0.05)	$ (0.05)
Weighted average number of shares outstanding—basic and diluted	60,666	66,528	71,103	71,781

	2019			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 21,533	$ 18,374	$ 20,918	$ 27,196
Gross profit	$ 5,863	$ 6,573	$ 7,050	$ 9,117
Loss from operations	$ (10,910)	$ (11,910)	$ (10,288)	$ (8,706)
Net loss	$ (12,080)	$ (13,308)	$ (11,675)	$ (10,287)
Net loss per share:				
Net loss per share—basic and diluted	$ (0.21)	$ (0.23)	$ (0.20)	$ (0.17)
Weighted average number of shares outstanding—basic and diluted	56,581	57,171	57,718	58,915

	2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 20,645	$ 14,941	$ 15,795	$ 19,378
Gross profit	$ 4,165	$ 4,414	$ 5,630	$ 5,272
Loss from operations	$ (10,790)	$ (15,802)	$ (10,568)	$ (10,612)
Net loss	$ (11,423)	$ (16,521)	$ (10,993)	$ (11,563)
Net loss per share:				
Net loss per share—basic and diluted	$ (0.21)	$ (0.30)	$ (0.20)	$ (0.21)
Weighted average number of shares outstanding—basic and diluted	55,205	55,547	55,847	56,065

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports we file under the Securities Exchange Act of 1934, as amended ("Exchange Act"), is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2020, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred in the quarter ended December 31, 2020 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of GenMark Diagnostics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited GenMark Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the "COSO criteria"). In our opinion, GenMark Diagnostics, Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 25, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP
San Diego, California
February 25, 2021

ITEM 9B. OTHER INFORMATION

None.

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our definitive proxy statement filed in connection with our 2021 Annual Meeting of Stockholders or an amendment to this Form 10-K to be filed with the SEC within 120 days after the close of our fiscal year ended December 31, 2020.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Annual Report.

1. The following financial statements of GenMark Diagnostics, Inc. and Report of Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b) Exhibits

Exhibit	Description
3.1	Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 filed with the SEC on March 19, 2010).
3.2	Amended and Restated Bylaws (incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 2, 2018).
4.1	Description of Registrant's Securities (incorporated by reference herein from our Form 10-K filed with the SEC on March 2, 2020).
10.1	Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 8, 2010 (incorporated by reference to our Registration Statement on Form S-1 filed with the Commission on March 19, 2010).
10.2	Settlement and Release Agreement and First Amendment to Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc., dated July 1, 2010 (incorporated by reference herein form our Form 10-K as filed with the SEC on March 14, 2013).
10.3	Settlement and Release Agreement and Second Amendment to Lease, dated January 19, 2012, by and between the Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 21, 2012).
10.4	Second Amendment to License Agreement dated June 20, 2000 by and between California Institute of Technology and Clinical Micro Sensors, Inc. (incorporated by reference herein form our Form 10-K/A as filed with the SEC on April 18, 2013). †
10.5	Third Amendment to Lease Agreement dated August 28, 2012, by and between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on November 8, 2012).
10.6	Fourth Amendment to Lease Agreement dated July 24, 2018, by and between The Campus Carlsbad LLC and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on July 30, 2018).
10.7	Non-Exclusive License Agreement by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Caliper Life Sciences Inc. dated effective as of March 27, 2012 (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 10, 2012). †
10.8	Development Collaboration and License Agreement, dated July 26, 2012, by and between Advanced Liquid Logic, Inc. and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q/A as filed with the SEC on March 22, 2013). †
10.9	Amendment Number One to Development Collaboration and License Agreement, effective as of January 18, 2016, by and among Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc., Advanced Liquid Logic, Inc., and Illumina, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 3, 2016). †
10.10	Loan and Security Agreement dated as of February 1, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on April 30, 2019). †
10.11	First Amendment to Loan and Security Agreement dated as of October 29, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders (incorporated by reference herein from our Form 10-K filed with the SEC on March 2, 2020). †
10.12	Second Amendment to Loan and Security Agreement dated as of December 16, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders (incorporated by reference herein from our Form 10-K filed with the SEC on March 2, 2020). †
10.13	Third Amendment to Loan and Security Agreement dated as of February 27, 2020 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders (incorporated by reference herein from our Form 10-K filed with the SEC on March 2, 2020). †
10.14	Manufacturing and Supply Agreement, dated December 15, 2015, by and between Plexus Corp. and Clinical Micro Sensors, Inc. d.b.a GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-K filed with the SEC on February 28, 2017).
10.15	Form of Restricted Stock Units Agreement under the 2020 Plan (incorporated by reference herein to our Form 8-K as filed with the SEC on June 2, 2020). *
10.16	Form of Amendment of Restricted Stock Unit And/Or Stock Option Agreement(s) (incorporated by reference herein to our Form 8-K as filed with the SEC on June 2, 2020). *
10.17	Form of Market Stock Units Grant Notice and Award Agreement (incorporated by reference herein from our Form 10-Q filed with the SEC on May 5, 2015). *

Exhibit	Description
10.18	GenMark Diagnostics, Inc. 2020 Bonus Plan (incorporated by reference to our Current Report on Form 8-K filed with the SEC on March 2, 2020).
10.19	GenMark Diagnostics, Inc. 2020 Equity Incentive Plan, as amended (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 15, 2020). *
10.20	GenMark Diagnostics, Inc. 2010 Equity Incentive Plan, as amended (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 17, 2014). *
10.21	Form of Stock Option Agreement (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010). *
10.22	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010). *
10.23	Form of Restricted Stock Units Grant Notice and Agreement (incorporated by reference herein to our Form 8-K as filed with the SEC on March 12, 2013). *
10.24	Form of Amendment of Restricted Stock, Restricted Stock Unit and/or Stock Option Agreement(s) (incorporated by reference herein to our Form 10-K filed with the SEC on February 28, 2017). *
10.25	GenMark Diagnostics, Inc. 2013 Employee Stock Purchase Plan, as amended (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed with the Commission on April 13, 2018). *
10.26	Form of Director and Officer Indemnification Agreement (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010). *
10.27	Separation Agreement and General Release, dated as of April 25, 2020, by and between GenMark Diagnostics, Inc. and Hany Massarany (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 4, 2020). *
10.28	Amended and Restated Executive Employment Agreement dated as of June 1, 2020 by and between GenMark Diagnostics, Inc. and Scott Mendel (incorporated by reference to our Current Report on Form 8-K filed with the SEC on June 2, 2020). *
10.29	The Separation Agreement and General Release made between James McNally and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc (incorporated by reference herein from our Form 10-K filed with the SEC on March 2, 2020). *
10.30	GenMark Diagnostics, Inc. Non-Plan Stock Option Agreement with Scott Mendel (incorporated by reference to our Registration Statement on Form S-8 (File No. 333-195924) filed with the SEC on May 13, 2014). *
10.31	GenMark Diagnostics, Inc. Non-Plan Restricted Stock Units Agreement with Scott Mendel (incorporated by reference to our Registration Statement on Form S-8 (File No. 333-195924) filed with the SEC on May 13, 2014). *
10.32	Equity Distribution Agreement dated August 5, 2019, by and among, GenMark Diagnostics, Inc. and Canaccord Genuity LLC (incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 5, 2019).
10.33	Single Tenant Industrial Triple Net Lease dated July 2, 2020 by and between GenMark Diagnostics, Inc. and Icon Owner Pool 1 West/Southwest, LLC (incorporated by reference herein from our Form 10-Q as filed with the SEC on October 28, 2020).†
10.34	General Release of Claims dated September 14, 2020 by and between Brian Mitchell and GenMark Diagnostics, Inc (incorporated by reference herein from our Form 10-Q as filed with the SEC on October 28, 2020).*
21.1	List of Subsidiaries (incorporated by reference to our Form 10-K as filed with the SEC on February 24, 2015).
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. ü
24.1	Power of Attorney (included on the signature page hereto). ü
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.

Exhibit	Description
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

ü Included in this filing.

† Pursuant to SEC rules, certain confidential portions of such document have been omitted.

* Indicates a management contract or compensatory plan or arrangement in which any director or named executive officer participates.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

GENMARK DIAGNOSTICS, INC.

Date: February 25, 2021

By: /s/ SCOTT MENDEL
Scott Mendel
President, Chief Executive Officer, and Director
(Principal Executive Officer)

Date: February 25, 2021

By: /s/ JOHNNY EK
Johnny Ek
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Scott Mendel and Johnny Ek, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/S/ SCOTT MENDEL **Scott Mendel**	President, Chief Executive Officer, and Director (Principal Executive Officer)	February 25, 2021
/S/ JOHNNY EK **Johnny Ek**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2021
/S/ KEVIN O'BOYLE **Kevin O'Boyle**	Chair of the Board	February 25, 2021
/S/ DARYL J. FAULKNER **Daryl J. Faulkner**	Director	February 25, 2021
/S/ JAMES FOX **James Fox**	Director	February 25, 2021
/S/ MICHAEL S. KAGNOFF **Michael S. Kagnoff**	Director	February 25, 2021
/s/ LISA M. GILES **Lisa M. Giles**	Director	February 25, 2021

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-228486) of GenMark Diagnostics, Inc.,
(2) Registration Statement (Form S-8 No. 333-189348) pertaining to the 2013 Employee Stock Purchase Plan of GenMark Diagnostics, Inc.,
(3) Registration Statement (Form S-8 No. 333-225285) pertaining to the Amended and Restated 2013 Employee Stock Purchase Plan of GenMark Diagnostics, Inc.,
(4) Registration Statements (Form S-8 Nos. 333-168892, 333-182268, 333-187393, 333-194514, 333-202286, 333-209688, 333-216387, 333-223357, 333-229884 and 333-236865) pertaining to the 2010 Equity Incentive Plan of GenMark Diagnostics, Inc.,
(5) Registration Statement (Form S-8 No. 333-195924) pertaining to the GenMark Diagnostics, Inc. Non-Plan Stock Option Agreement with Scott Mendel and GenMark Diagnostics, Inc. Non-Plan Restricted Stock Units Agreement with Scott Mendel, and
(6) Registration Statement (Form S-8 No. 333-238812) pertaining to the 2020 Equity Incentive Plan of GenMark Diagnostics, Inc.;

of our reports dated February 25, 2021, with respect to the consolidated financial statements of GenMark Diagnostics, Inc. and the effectiveness of internal control over financial reporting of GenMark Diagnostics, Inc. included in this Annual Report (Form 10-K) of GenMark Diagnostics, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Diego, California
February 25, 2021

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Scott Mendel, certify that:

1. I have reviewed this Annual Report on Form 10-K of GenMark Diagnostics, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Scott Mendel
Scott Mendel
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER

Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Johnny Ek, certify that:

1. I have reviewed this Annual Report on Form 10-K of GenMark Diagnostics, Inc.;

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

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

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

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Johnny Ek
Johnny Ek
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

Each of the undersigned, in his capacity as the principal executive officer and principal financial officer of GenMark Diagnostic, Inc. (the "Company"), as the case may be, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that, to the best of his knowledge:

1. This Annual Report on Form 10-K for the period ended December 31, 2020 (this "Annual Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by this Annual Report.

Date: February 25, 2021

By: /s/ Scott Mendel
Scott Mendel
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 25, 2021

By: /s/ Johnny Ek
Johnny Ek
Chief Financial Officer
(Principal Financial and Accounting Officer)

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