GenMark Diagnostics, Inc.
Form 10-K
February 25, 2019
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the year ended December 31, 2018

¨ 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	92008-8829
(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:	Name of Each Exchange on which Registered:
Common Stock, par value $0.0001 per share	The NASDAQ Stock Market LLC (NASDAQ Global Market)

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

---

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933, as amended. YES ¨ NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended. YES ¨ NO x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨
Emerging growth company	¨		

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

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

As of June 30, 2018, 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 $334,688,000 based on the closing sale price for the registrant's common stock on the NASDAQ Global Market on that date of $6.38 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 21, 2019 was 56,472,425. The common stock is listed on the NASDAQ Global Market (trading symbol "GNMK").

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year are incorporated by reference into Part III of this report.

Table of Contents

TABLE OF CONTENTS

1

Table of Contents

Forward-Looking Statements

This Annual Report on Form 10-K, or 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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,” “e “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®, XT-8®, ePlex® 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 and 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.

Table of Contents

PART I.

Item 1. BUSINESS

GenMark Diagnostics, Inc., or 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 received 510(k) market clearance from the FDA for our ePlex Blood Culture Identification Gram-Positive (BCID-GP) and Blood Culture Identification Fungal Pathogen (BCID-FP) Panels in December 2018. We submitted a 510(k) application to the FDA for our ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel in September 2018. We are also developing our ePlex Gastrointestinal Pathogen 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, 2018, 2017 and 2016 were approximately $50.5 million, $61.9 million, and $50.6 million, respectively. As of December 31, 2018, we had an accumulated deficit of $466.9 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.

Table of Contents

- 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 Gastrointestinal Pathogen 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, which our ePlex system is uniquely positioned to address.
- 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 and health economic utility of multiplex molecular diagnostic panels, which we believe will increase 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 solution 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 and customer education and training.

Revenues, net loss, and total assets for the past three years are contained in our consolidated financial statements in Part II of this Annual Report. Substantially all of our revenues for the periods reported in our consolidated financial statements in Part II of this Annual Report were derived from customers located within the United States.

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, a proprietary label, 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.

Table of Contents

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. In June 2017, we received 510(k) market clearance from the FDA for both our ePlex instrument and ePlex RP Panel. We received 510(k) market clearance from the FDA for our ePlex BCID-GP and BCID-FP panels in December 2018. We submitted a 510(k) application to the FDA for our ePlex BCID-GN Panel in September 2018. In addition, we are developing our ePlex Gastrointestinal Pathogen Panel for the detection of pathogens associated with gastrointestinal infections. We also 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 $2.5 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.

Table of Contents

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 87,000 square feet at two 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 select 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 based in Europe.

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 and our launch plans for our ePlex system, we continue to make investments in these customer facing organizations.

Table of Contents

Our sales cycle typically includes customer evaluations and validations of our products. Upon successful validation, a customer will generally acquire our instrument in 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 laboratories and 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 2018, 2017, and 2016, Laboratory Corporation of America, Inc. represented 16%, 20% and 27%, 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, 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, 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 exclusively licensed U.S. and foreign patents and approximately 50 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 2028 and 2038.

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.

Table of Contents

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®, XT-8®, and ePlex®, 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, or 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 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, and BCID-FP Panels. In addition, we submitted a 510(k) application to the FDA for our ePlex BCID-GN Panel in September 2018.

Proposed Regulation of Laboratory Developed Tests (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 even reporting, quality system regulation, or 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.

Table of Contents

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 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, or 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 and 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

Table of Contents

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 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. We are unable to predict whether the suspension will be continued beyond 2020. Taxable devices include any medical device defined in section 201(h) of the FDCA and intended for use by humans, with limited exclusions for devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we paid the tax from January 2013 through December 2015. The Health Care Act also 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

As of December 31, 2018, we had 477 employees, of which: 87 employees were involved in research and development; 278 were involved in operations, manufacturing, and quality assurance; 70 were involved in sales and marketing; and 42 were involved in general and administrative functions. Our success will depend in large part upon our ability to attract and retain employees. We face competition in this regard from other companies, research and academic institutions, government entities, and other organizations. 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 the flu season. 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 nearby to 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, or the 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.

Table of Contents

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.

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, testing capacity and flexibility, and 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 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.

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.

Table of Contents

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 intensity of competition 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 (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 NV; bioMérieux; Roche Diagnostics; and Abbott Molecular Diagnostics.

Our diagnostic test panels also face competition from laboratory developed tests (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.

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.

Table of Contents

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

In June 2016, we obtained CE Mark under the European In-Vitro Diagnostic Devices Directive (98/79/EC) for our ePlex instrument and ePlex RP Panel; in April 2017, we obtained CE Mark for our ePlex BCID-FP Panel; and in June 2017, we obtained CE Mark for our ePlex BCID-GP Panel and BCID-GN 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 based in Europe. 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.

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 Panel 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.

In addition, efforts to reform the healthcare delivery system in the United States and Europe has 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.

Table of Contents

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. 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. 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, and/or availability 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.

Finding solutions to product quality, reliability, variability, and raw material sourcing issues are 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 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 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 customers 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 customers 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;

Table of Contents

- 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 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, 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.

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. Plexus specializes in the manufacturing of electronic and electro-mechanical devices. We outsource the manufacture of our ePlex instrument to 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. 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.

Table of Contents

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 new 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.

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. Influenza and other respiratory-related outbreaks are usually more concentrated in the first and fourth quarters of the year. 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 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.

Also, unanticipated changes in customer demand for our products may result in constraints or inefficiencies related to our manufacturing, sales force, customer service and administrative infrastructure. These constraints or inefficiencies may adversely affect us as a result of delays, lost potential product sales or loss of current or potential customers due to their dissatisfaction.

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

Our largest customer, Laboratory Corporation of America, Inc., accounted for approximately 16% of our total revenue for the fiscal year ended December 31, 2018. 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.

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 tests;
- 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 from third parties to expand the menu of diagnostics tests 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.

Table of Contents

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products, as well as our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with our ePlex system. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our business and financial condition.

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 are investing significantly in the development of new ePlex molecular diagnostic tests to expand our future product offerings. Our newly developed ePlex test panels will require 510(k) clearance or pre-market approval by the FDA prior to marketing those tests for commercial use in the United States. We obtained 510(k) clearance from the FDA for our ePlex BCID-GP and BCID-FP panels in December 2018. We also submitted our ePlex BCID-GN Panel to the FDA for 510(k) clearance in September 2018. 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 newly developed 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, or 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, or IVDR. Under the IVDR, the classification 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 Notified Body conformity assessments according to the IVDD. 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. The FDA has traditionally practiced enforcement discretion regarding the use of the LDTs for clinical diagnostic purposes. However, the FDA has promulgated draft guidance which outlines stringent regulatory requirements for CLIA labs in order to use LDTs for clinical diagnostic application. 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.

Table of Contents

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, or, CMS, released the final rule implementing the federal Physician Payments Sunshine Act, or 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. We expect compliance with the Sunshine Act to impose significant administrative and financial burdens on us.

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, or 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, or 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 devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we paid the tax from 2013 through 2015. Recently, Congress and the new 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.

Table of Contents

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 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 exclusively licensed patents and approximately 50 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 2028 and 2038. 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.

Table of Contents

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 any of 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 Quality System Regulation, or 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.

Table of Contents

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 $50.5 million, $61.9 million and $50.6 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $466.9 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.

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.

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

21

Table of Contents

Global economic conditions may remain challenging and uncertain for the foreseeable future. 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 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.

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.

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

Table of Contents

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.

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.

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

As of December 31, 2018, we had net operating loss, or NOL, carryforwards available of approximately $306.8 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2037. Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or 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 $215 million as of December 31, 2018. We have recorded a full valuation allowance against our net deferred tax assets.

Table of Contents

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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We currently operate from two facilities, each of which is 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.

In June 2015, we leased an additional 34,000 square feet at a nearby location in Carlsbad, California, which we utilize primarily for ePlex manufacturing operations. The term of this lease runs through September 2023, and we have an option to extend the term of the lease for an additional five years. We believe that our currently leased facilities are adequate to meet our needs for the foreseeable future.

Table of Contents

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.

Table of Contents

PART II.

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

Market Information

Our common stock has been quoted on The NASDAQ Global Market under the symbol "GNMK" since May 28, 2010. The following table sets forth for the indicated periods the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market.

	High	Low
Year Ended December 31, 2018		
First Quarter	$5.87	$4.01
Second Quarter	$7.70	$5.02
Third Quarter	$8.56	$5.96
Fourth Quarter	$7.00	$3.74
Year Ended December 31, 2017		
First Quarter	$13.62	$9.80
Second Quarter	$13.67	$11.45
Third Quarter	$12.55	$8.88
Fourth Quarter	$9.87	$3.63

Table of Contents

Stock Performance Graph

The graph below compares the cumulative total stockholder returns on our common stock, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index for the five years ended December 31, 2018. The graph assumes that $100 was invested in the Company's common stock and in each index as of the market close on December 31, 2013 and that all dividends were reinvested. No cash dividends have been declared on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

Stockholders

The last reported sale price of our common stock on February 21, 2019 as reported on the NASDAQ Global Market was $6.82. As of February 21, 2019, there were 965 holders of record of our common stock.

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.

Table of Contents

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, 2018, 2017, and 2016 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2018 and 2017 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, or U.S. GAAP, included elsewhere in this Annual Report. The selected consolidated statement of comprehensive loss data presented for the years ended December 31, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016, 2015, and 2014 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 together with the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section and with the consolidated financial statements and condensed consolidated financial statements of GenMark Diagnostics, Inc. and related notes included elsewhere in this Annual Report.

Table of Contents

FIVE YEAR SELECTED FINANCIAL DATA

	Years ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statements of Comprehensive Loss Data:	(In thousands, except per share data)				
Revenue					
Product revenue	$70,481	$52,260	$48,914	$39,029	$30,328
License and other revenue	278	259	360	382	266
Total revenue	70,759	52,519	49,274	39,411	30,594
Cost of revenue	51,278	32,514	19,700	15,317	13,127
Gross profit	19,481	20,005	29,574	24,094	17,467
Operating expenses:					
Sales and marketing	21,777	20,557	14,734	14,385	12,629
General and administrative	17,545	16,205	14,363	13,772	12,069
Research and development	27,931	42,760	49,458	37,472	31,823
Total operating expenses	67,253	79,522	78,555	65,629	56,521
Loss from operations	(47,772)	(59,517)	(48,981)	(41,535)	(39,054)
Other income (expense):					
Interest income	711	561	176	125	244
Interest expense	(3,108)	(3,042)	(1,536)	(880)	(20)
Other income (expense)	(192)	249	(160)	133	(6)
Total other income (expense)	(2,589)	(2,232)	(1,520)	(622)	218
Loss before provision for income taxes	(50,361)	(61,749)	(50,501)	(42,157)	(38,836)
Income tax expense (benefit)	139	101	100	40	(573)
Net loss	$(50,500)	$(61,850)	$(50,601)	$(42,197)	$(38,263)
Net loss per share, basic and diluted	$(0.91)	$(1.21)	$(1.15)	$(1.00)	$(0.93)
Weighted average number of shares outstanding basic and diluted	55,669	51,169	44,100	42,157	41,346

	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and marketable securities (1)(2)	$45,168	$71,990	$41,566	$45,465	$70,506
Total assets	92,981	122,299	80,324	70,667	91,970
Long-term liabilities	39,147	23,399	15,752	11,481	1,653
Total liabilities	59,434	51,142	42,173	22,070	13,946
Accumulated deficit	(466,883)	(416,383)	(355,270)	(304,669)	(262,472)
Total stockholders' equity (1)(2)	33,547	71,157	38,151	48,597	78,024

(1) 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.

(2) 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.

Table of Contents

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 was formed by Osmetech plc, or Osmetech, as a Delaware corporation in February 2010, and had no operations prior to its initial public offering, which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure. The liquidation of Osmetech was competed in the fourth quarter of 2013.

We are 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. 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, 2018, 2017, and 2016 were approximately $50.5 million, $61.9 million, and $50.6 million, respectively. As of December 31, 2018, we had an accumulated deficit of $466.9 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 menu for our ePlex instrument, as well as to further increase our manufacturing capabilities and commercial organization.

Our Products and Technology

We offer our ePlex sample-to-answer instrument and Respiratory Pathogen (RP) Panel, BCID-GP Panel, and BCID-FP Panel for sale in the United States and internationally. We have obtained CE Mark for our ePlex BCID-GN Panel and we submitted a 510(k) application to the FDA for our BCID-GN Panel in September 2018. We are also developing our ePlex Gastrointestinal Pathogen 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).

Revenue

Revenue from operations includes product sales, principally of our diagnostic panels. We primarily place our instruments with customers through a reagent rental agreement, under which we retain title to the instrument and customers commit to purchasing minimum quantities of reagents and test cartridges over a period of one to five years. We also offer our instruments for sale.

Cost of Revenues

Table of Contents

Cost of revenues includes the cost of materials, direct labor, and manufacturing overhead costs used in the manufacture of our consumable tests, including royalties on product sales. 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, technical 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. We expect sales and marketing expenses to continue to increase as we scale-up our domestic and international commercial efforts and expand our customer base.

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, contract research organization costs, 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 resource, administrative, and investor relations activities. These expenses consist primarily of salaries, benefits, stock-based compensation costs, independent auditor costs, legal fees, consultants, insurance, 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 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.

Table of Contents

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.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue

The Company recognizes revenue from operations through the sale of products and other services. Product revenue is comprised of the sale of diagnostic tests and instruments and is recorded net of discounts and sales taxes collected on behalf of governmental authorities.

We recognize revenue from product sales and contractual arrangements when the control of products and services are 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.

We offer customers the choice to either purchase an instrument outright or to receive possession of an instrument free of charge in exchange for a commitment to purchase an annual minimum amount of molecular diagnostic test cartridges.

When an instrument or diagnostic test is sold, revenue is generally recognized upon shipment of the unit consistent with contract terms and when control of the product is deemed to be transferred. Revenue from instrument services is recognized as the services are rendered, typically evenly over the contract term.

When an instrument is placed free of charge under a reagent rental agreement, we retain title to the instrument and it remains capitalized on our balance sheet under property and equipment. Under our reagent rental agreements, our customers pay an instrument usage fee, which is included in the price of each test cartridge purchased. Our reagents and diagnostic test cartridges (consumables) are priced to include the expense of instrument usage and maintenance and are included in product revenue in our consolidated financial statements.

We sell our durable instruments and disposable test cartridges through a direct sales force in the United States and certain international countries and through distributor arrangements in other European jurisdictions. Employee sales commissions are recorded as selling and marketing expenses when incurred or amortized over the estimated contract term when resulting from new contract acquisition efforts.

Allowance for Doubtful Accounts Receivable

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. Our allowance for doubtful accounts is based on our assessment of the collectability of specific customer accounts, the aging of accounts receivable, and the general condition of the economy. Changes in our allowance for doubtful accounts are charged to sales and marketing expense.

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 and 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 12 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.

Table of Contents

Property and Equipment — Net

Property, equipment, and leasehold improvements are recorded at cost and depreciated using the straight-line method over the assets' estimated useful lives, which are noted below. Each category of property and equipment is analyzed to determine its useful life. We look at the manufacturers' estimates of useful life and adjust these for actual experience in our operating environment. Useful lives are reviewed periodically and occasionally changed as circumstances dictate.

Machinery and laboratory equipment	3 - 5 years
Instruments	4 - 5 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

Repair and maintenance costs are expensed as incurred. During 2018, 2017, and 2016, we disposed of certain assets no longer in use with a net book value of $501,000, $207,000 and $76,000, respectively, recorded to cost of revenue, sales and marketing, research and development, or general and administrative expenses based on the asset's respective use.

Impairment of Long-Lived Assets

We assess the recoverability of long-lived assets, including intangible assets and instruments at customer locations by periodically evaluating the carrying value of such assets whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. If impairment is indicated, we write down the carrying value of the asset to the estimated fair value.

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. The 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 is based on published government rates in effect at the time of grant for periods corresponding with the expected term of the option or award.

Income Taxes

Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's best assessment of estimated future taxes to be paid. We file income tax returns in the United States,

Switzerland, Germany, the United Kingdom, France, and various state jurisdictions. Significant judgments and estimates are required in determining our consolidated income tax expense.

We believe that it is more likely than not that the benefit from our deferred tax assets will not be realized. In recognition of this risk, we have provided a full valuation allowance on the net deferred tax assets relating to our net operating loss carryforwards and other deferred tax assets. If our assumptions change and we determine that we will be able to realize our deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets will be accounted for as a reduction of income tax expense. Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future.

Table of Contents

We recognize tax liabilities in accordance with Accounting Standards Codification, or ASC, Topic 740 and we adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the tax liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which they are determined.

Recent Accounting Pronouncements

For a summary of recent accounting pronouncements applicable to our consolidated financial statements, see Note 2, "Summary of Significant Accounting Policies and Significant Accounts" to the Consolidated Financial Statements in Part II, Item 8 of this Annual Report.

Results of Operations

Comparison of Years Ended December 31, 2018, 2017 and 2016 (tables in thousands):

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Revenue	$70,759	$52,519	49,274	$18,240	35 %	$3,245	7 %

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

Revenue increased by $18.2 million, or 35%, when comparing the years ended December 31, 2018 and 2017, driven by growth in ePlex product revenue relative to XT-8 product revenue. For the year ended December 31, 2018, ePlex product revenue increased by $27.7 million to $37.9 million due to both new customers adopting ePlex and the conversion of existing XT-8 customers to our ePlex system for respiratory testing. ePlex consumable revenue represented approximately 90% of total ePlex product revenue during the year ended December 31, 2018. XT-8 revenue decreased by $9.5 million to $32.6 million during the year ended December 31, 2018 primarily due to customers converting to the ePlex sample-to-answer system for respiratory testing.

Revenue increased by $3.2 million, or 7% , when comparing the years ended December 31, 2017 and 2016. For the year ended December 31, 2017, ePlex product revenue increased by $8.7 million to $10.2 million due to the ePlex sample-to-answer instrument and RP panel receiving 510(k) market clearance from the FDA during the second half of 2017 and the conversion of existing XT-8 customers to ePlex for respiratory testing. ePlex consumable revenue represented approximately 64.1% of total ePlex product revenue during the year ended December 31, 2017. XT-8 revenue decreased by $5.3 million to $42.1 million during the year ended December 31, 2017 due to customers converting to the ePlex sample-to-answer system for respiratory testing.

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Cost of Revenue	$51,278	$32,514	$19,700	$18,764	58 %	$12,814	65 %
Gross Profit	$19,481	$20,005	$29,574	$(524)	(3)%	$(9,569)	(32)%

The increase in cost of revenue for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to higher overall product revenue and specifically, the growth in ePlex product revenue relative to XT-8 product revenue. The higher manufacturing cost profile of the ePlex platform reflects the additional technology and features of its sample-to-answer capabilities coupled with its early product life cycle. Costs of revenue

increased by $18.8 million during the year ended December 31, 2018 driven by the sales growth of the ePlex system with this higher cost profile relative to the XT-8 system. In addition to this shift in product mix, other changes in our cost of revenue included increases in inventory reserves of $367 thousand and freight expense of $315 thousand as a result of higher sales, partially offset by decreases in customer and product technical support costs of $722 thousand. The decrease in gross profit of $524 thousand is primarily attributable to higher cost of revenue.

Table of Contents

The increase in cost of revenue for the year ended December 31, 2017 compared to the year ended December 31, 2016 was attributable to the growth in ePlex product revenue relative to XT-8 product revenue and investments to expand our manufacturing capabilities to support the continued commercialization of the ePlex system. Cost of revenue increased during the year ended December 31, 2017 by $9.4 million driven by the higher manufacturing cost profile of the ePlex system coupled with its early product life cycle. Other changes in cost of revenue included an increase of $3.3 million in customer and product technical support for customers adopting the ePlex system.

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Sales and Marketing	$21,777	$20,557	$14,734	$1,220	6 %	$5,823	40 %

The increase in sales and marketing expense for the year ended December 31, 2018 compared to the year ended December 31, 2017 is primarily related to increased sample kit expense of $493 thousand resulting from new system implementations, increased depreciation expense of $307 thousand associated with ePlex systems under evaluation at customer locations, increased employee-related expense of $125 thousand from higher headcount, and increased supplies expense of $135 thousand due to auxiliary equipment provided to customers.

The increase in sales and marketing expense for the year ended December 31, 2017 when compared to the year ended December 31, 2016 was primarily driven by increased employee-related expense of $3.9 million due to increased headcount, increased travel expenses of $428 thousand, increased supplies and equipment of $966 thousand associated with additional instrument placements, increased marketing expense of $224 thousand associated with the commercial launch of the ePlex system, and increased outside service expense of $221 thousand, primarily related to increased activity associated with our international distribution center.

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
General and Administrative	$17,545	$16,205	$14,363	$1,340	8 %	$1,842	13 %

The increase in general and administrative expense for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily related to increased professional service expense of $729 thousand due to timing of work performed and increased employee-related expense of $662 thousand due to higher employee bonuses.

The increase in general and administrative expense for the year ended December 31, 2017 compared to the year ended December 31, 2016 was primarily driven by increased employee-related expenses of $1.3 million, including a $1.1 million increase in stock-based compensation expense, increased travel expense of $147 thousand, and increased consulting services of $411 thousand, partially offset by decreased audit and tax expense of $281 thousand due to timing of work performed, and decreased facility and supplies expense of $303 thousand.

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Research and Development	$27,931	$42,760	$49,458	$(14,829)	(35)%	$(6,698)	(14)%

The decrease in research and development expense for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily driven by a decrease of $14.1 million in supplies and prototype materials used by our assay development team and a $2.6 million decrease in employee-related expense due to decreased headcount, partially offset by an $839 thousand increase in clinical study expense due to the timing of the ePlex BCID clinical studies and $987 thousand in increased facility and information technology expense.

The increase in research and development expense for the year ended December 31, 2017, compared to the year ended December 31, 2016, was primarily driven by decreased ePlex system development expense of $10.1 million, decreased clinical trial expense of $392 thousand due to the timing of trials, decreased repairs and maintenance expense of $303 thousand, and decreased freight expense of $514 thousand, partially offset by increased supplies and prototype materials utilized by our assay development teams of $4.4 million and increased intellectual property prosecution and maintenance expense of $206 thousand.

Table of Contents

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Other Income (Expense)	$(2,589)	$(2,232)	$(1,520)	$(357)	16 %	$(712)	47 %

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

The change in other income (expense) for the year ended December 31, 2018, compared to the year ended December 31, 2017, was primarily due to less favorable foreign currency fluctuations of $438 thousand and increased interest expense of $66 thousand on amounts due under our debt facility, partially offset by increased interest income of $150 thousand.

The change in other income (expense) for the year ended December 31, 2017, compared to the year ended December 31, 2016, was primarily due to increased interest expense of $1.5 million on amounts due under our debt facility, partially offset by increased interest income of $385 thousand and an increase of $415 thousand related to foreign currency fluctuations.

	Years ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016	$ Change	% Change	$ Change	% Change
Income Tax Expense	$139	$101	$100	$38	38 %	$ 1	1 %

Due to net losses incurred, the tax provisions recorded relate to minimum tax payments in the United States and tax liabilities generated by our foreign subsidiaries. Income tax expense for the year ended December 31, 2018, compared to the year ended December 31, 2017, remained consistent and related primarily to international income taxes. Income taxes remained consistent when comparing the years ended December 31, 2017 and 2016.

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 operations each year and have not yet achieved profitability. As of December 31, 2018, we had $48.1 million of working capital, including $45.2 million in cash, cash equivalents, and marketable securities.

Cash Flows

The following table shows cash flow information for the years ended December 31, 2018, 2017 and 2016:

	Years Ended December 31,		
	2018	2017	2016
Cash used in operating activities	$(32,512)	$(53,422)	$(35,637)
Cash provided by (used in) investing activities	33,947	(24,908)	(24,123)
Cash provided by financing activities	8,069	89,050	40,359
Effect of exchange rate changes on cash	28	75	(25)
Net increase (decrease) in cash and cash equivalents	$9,532	$10,795	$(19,426)

Cash flows used in operating activities

Net cash used in operating activities decreased by $20.9 million for the year ended December 31, 2018 compared to the prior year. The decrease in cash used in operating activities was primarily due to a $11.4 million decrease in net

loss, a $8.2 million increase from changes in operating assets and liabilities, and a $1.4 million increase in non-cash adjustments. The increase in non-cash adjustments is primarily related to an increase of $1.8 million in depreciation and amortization expense and a $239 thousand increase in other non-cash adjustments, partially offset by decreases of $473 thousand in stock-based compensation expense and $194 thousand in amortization expense of debt issuance costs.

Table of Contents

Net cash used in operating activities increased by $17.8 million for the year ended December 31, 2017, compared to the prior year. The increase in cash used in operating activities was primarily due to an $11.2 million increase in net loss and a $12.3 million increase from changes in operating assets and liabilities.These increases were partially offset by non-cash adjustments of $5.8 million, including increased stock-based compensation expense of $2.9 million, an increase in depreciation and amortization expense of $1.4 million and non-cash adjustments to inventory of $1.2 million.

Cash flows provided by (used in) investing activities

Net cash provided by investing activities increased by $58.9 million for the year ended December 31, 2018 compared to the prior year. The increase in net cash provided by investing activities was primarily due to increases in the net sales of marketable securities of $27.3 million, decreases in purchases of property, plant, and equipment of $2.2 million, decreases in intellectual property milestone payments of $500 thousand, and increases in the maturities of marketable securities of $28.8 million.

Net cash used in investing activities for the year ended December 31, 2017, compared to the year ended December 31, 2016, increased $785 thousand primarily due to an increase in net purchases and sales of marketable securities of $31.4 million, partially offset by decreases in purchases of property, plant, and equipment of $2.2 million, intellectual property milestone payments of $1 million, and the maturities of marketable securities of $27.5 million.

Cash flows provided by financing activities

Net cash provided by financing activities decreased by $81 million for the year ended December 31, 2018 compared to the prior year. The decrease in cash provided by financing activities was primarily due to a net decrease in proceeds from the sale of our common stock of $80.7 million and a decrease of $265 thousand in proceeds from stock option exercises.

Net cash provided by financing activities increased $48.7 million to $89.1 million for the year ended December 31, 2017, compared to $40.4 million for the year ended December 31, 2016, primarily due to a net increase in proceeds from the sale of our common stock of $52 million and an increase in net proceeds from debt issuance of $4.9 million, partially offset by an increase in the repayments of principal borrowings of $7.8 million and a decrease in proceeds from the exercise of employee stock options of $425 thousand.

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. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, and expand our research and development, commercialization, and manufacturing activities. 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;
- change in demand from our customers;
- the level of expenses required to expand our commercial (sales and marketing) and manufacturing 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

In January 2015, we entered into a Loan and Security Agreement, or the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other financial institutions party thereto, as lenders, pursuant to which we obtained up to $35,000,000 in a series of term loans and a revolving loan in the

maximum amount of $5,000,000. In the second half of 2018, we and the Lenders agreed to amend the LSA to provide us with two additional term loans of $663,000 and $7,098,000, respectively. As of December 31, 2018, we had borrowed all $42,762,000 under the term loans as provided in the LSA and had not borrowed any of the $5,000,000 available under the revolving loan. As of December 31, 2018, we were in compliance with all covenants under the LSA.

Table of Contents

On February 1, 2019, or the Effective Date, we entered into a Loan and Security Agreement, or the New LSA, with Solar Capital Ltd. and certain other financial institutions, or collectively, the Lenders. Pursuant to the New LSA, the Lenders are providing us with up to $65 million in a series of term loans, or the Term Loans, of which $50 million was funded on the Effective Date. An additional $15 million, or the Tranche 2 Loan, is available to be funded at our option, but no later than December 31, 2019, provided that we achieve a designated amount of product revenues on a trailing six-month basis, or the Tranche 2 Loan Funding Condition. On the Effective Date, we used approximately $38.8 million of the proceeds from the Tranche 1 Loan to repay all outstanding principal, interest, related fees, and other obligations under the LSA, with the remaining borrowings to be used to satisfy our working capital needs and for other general business purposes.

The Term Loans will 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 LIBOR 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, 2021, or the Interest Only Period. If (a) we timely satisfy the Tranche 2 Loan Funding Condition, (b) we exercise our option to borrow the Tranche 2 Loan, and (c) we achieve an additional designated amount of product revenues on a trailing six-month basis on or before December 31, 2020, then the Interest Only Period may, at our election, be extended for both Term Loans through February 28, 2022. Following the Interest Only Period (as the same may be extended pursuant to the terms of the New LSA), 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.

The New LSA 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 New 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 New LSA immediately due and payable and may exercise the other rights and remedies as set forth in the New LSA.

Common Stock Equity Offering

In June 2017, we entered into an Underwriting Agreement, or the Underwriting Agreement, with J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated acting as joint book-running managers and as representatives of the underwriters, or the Underwriters, relating to the issuance and sale of 6,382,978 shares of our common stock, or the Offering. The price to the public in the Underwriting Agreement was $11.75 per share, before underwriting discounts and commissions. Under the terms of the Underwriting Agreement, we granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 957,446 shares of our common stock.

The Offering was completed on June 19, 2017, pursuant to which we sold a total of 7,340,424 shares of our common stock for gross proceeds of $86,250,000. We incurred $5,175,000 in related transaction costs, comprised of underwriting discounts and commissions, and approximately $345,000 in additional miscellaneous offering expenses.

Equity Distribution Agreement

In June 2016, we entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity Inc., as sales agent, or Canaccord, pursuant to which we could, at our discretion, offer and sell, from time to time, through Canaccord shares of our common stock having an aggregate offering price of up to $30,000,000. Under the Distribution Agreement, Canaccord could sell shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 under the Securities Act or any other method permitted by law, including in privately negotiated transactions.

We began sales under the Distribution Agreement in August 2016 pursuant to an effective shelf registration statement on Form S-3 previously filed with the SEC. During the three months ended September 30, 2016, we sold 3.3 million shares of our common stock, at an average per share price of $9.04, for aggregate gross proceeds of $30,000,000. We incurred $1,143,000 in related transaction costs, comprising commissions paid to Canaccord of 3.0% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement, or $900,000, and $243,000 in additional miscellaneous expenses.

Letter of Credit

In September 2012, we provided a $758,000 letter of credit issued by Banc of California to the landlord of our executive office facility in Carlsbad, California. This letter of credit was secured with $758,000 of restricted cash at December 31, 2018.

Table of Contents

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 or 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.

Contractual Obligations

As of December 31, 2018, we had the following contractual obligations (in thousands):

	Payments due by period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Lease obligations (1)	$12,101	$ 1,989	$6,089	$3,322	$ 701
Licensing payment obligations	120	30	90	—	—
Debt obligations (2)	42,907	2,652	40,255	—	—
Total obligations	$55,128	$ 4,671	$46,434	$3,322	$ 701

(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 and real estate taxes. Our future operating lease obligations could change if we terminate certain contracts or if we enter into additional leases.

(2) The Company's contractual obligation under its LSA consists of principal payments, interest, and fees due to its lenders.

Impact of Inflation

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

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements. We have provided a $758,000 standby letter of credit to our landlord as security for future rent in connection the lease of our Carlsbad, California corporate headquarters, which is recorded as restricted cash on our consolidated balance sheet.

Table of Contents

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 of less than one year. 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.

Interest Rate Risk

As of December 31, 2018, based on current interest rates and 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.

Foreign Currency Exchange Risks

We are a U.S. entity and our functional currency is the U.S. dollar. Substantially all of our revenues were derived from sales in the United States. We have business transactions in foreign currencies, however, we believe we do not have significant exposure to risk from changes in foreign currency exchange rates at this time. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

Table of Contents

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, 2018 and 2017, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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, 2019 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.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2013.
San Diego, California
February 25, 2019

Table of Contents

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	As of December 31,	
	2018	2017
ASSETS:		
Current Assets:		
Cash and cash equivalents	$36,286	$26,754
Short-term marketable securities	8,882	45,236
Accounts receivable, net of allowances of $75 and $2,754, respectively	11,534	10,676
Inventories	10,244	10,949
Prepaid expenses and other current assets	1,483	2,216
Total current assets	68,429	95,831
Property and equipment, net	21,070	22,581
Intangible assets, net	2,023	2,624
Restricted cash	758	758
Other long-term assets	701	505
Total assets	$92,981	$122,299
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$9,886	$11,171
Accrued compensation	7,358	5,419
Current portion of long-term debt	—	7,927
Other current liabilities	3,043	3,226
Total current liabilities	20,287	27,743
Deferred rent	2,996	3,059
Long-term debt	36,042	20,099
Other noncurrent liabilities	109	241
Total liabilities	59,434	51,142
Commitments and contingencies - See Note 7		
Stockholders' equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 56,240 and 55,066 shares issued and outstanding, respectively	6	6
Additional paid-in capital	500,344	487,525
Accumulated deficit	(466,883)	(416,383)
Accumulated other comprehensive income	80	9
Total stockholders’ equity	33,547	71,157
Total liabilities and stockholders’ equity	$92,981	$122,299

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

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

	Years ended December 31,		
	2018	2017	2016
Revenue			
Product revenue	$70,481	$52,260	$48,914
License and other revenue	278	259	360
Total revenue	70,759	52,519	49,274
Cost of revenue	51,278	32,514	19,700
Gross profit	19,481	20,005	29,574
Operating expenses:			
Sales and marketing	21,777	20,557	14,734
General and administrative	17,545	16,205	14,363
Research and development	27,931	42,760	49,458
Total operating expenses	67,253	79,522	78,555
Loss from operations	(47,772)	(59,517)	(48,981)
Other income (expense):			
Interest income	711	561	176
Interest expense	(3,108)	(3,042)	(1,536)
Other income (expense)	(192)	249	(160)
Total other income (expense)	(2,589)	(2,232)	(1,520)
Loss before provision for income taxes	(50,361)	(61,749)	(50,501)
Income tax expense	139	101	100
Net loss	$(50,500)	$(61,850)	$(50,601)
Net loss per share, basic and diluted	$(0.91)	$(1.21)	$(1.15)
Weighted average number of shares outstanding basic and diluted	55,669	51,169	44,100
Other comprehensive loss			
Net loss	$(50,500)	$(61,850)	$(50,601)
Other comprehensive income/(loss):			
Foreign currency translation adjustments, net of tax	44	(84)	77
Net unrealized gains (losses) on marketable securities, net of tax	27	(2)	(11)
Total other comprehensive income/(loss)	71	(86)	66
Total comprehensive loss	$(50,429)	$(61,936)	$(50,535)

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Par Value				
Balance—December 31, 2015	42,551	$ 4	$ 353,233	$ 29	$ (304,669)	$ 48,597
Issuance of stock in lieu of accrued bonuses	28	—	364	—	—	364
Stock-based compensation expense	—	—	9,236	—	—	9,236
Issuance of employee stock purchase plan shares	138	—	921	—	—	921
Restricted stock awards issued, net of cancellations	421	—	—	—	—	—
Shares issued under stock-based compensation plans	99	—	712	—	—	712
Issuance of common stock, net of offering expenses	3,317	—	28,856	—	—	28,856
Net loss	—	—	—	—	(50,601)	(50,601)
Foreign currency translation adjustments	—	—	—	77	—	77
Unrealized loss on marketable securities	—	—	—	(11)	—	(11)
Balance—December 31, 2016	46,554	4	393,322	95	(355,270)	38,151
Stock-based compensation expense	—	—	12,170	—	—	12,170
Issuance of employee stock purchase plan shares	175	—	1,016	—	—	1,016
Restricted stock awards issued, net of cancellations	955	—	—	—	—	—
Shares issued under stock-based compensation plans	42	—	287	—	—	287
Issuance of common stock, net of offering expenses	7,340	2	80,730	—	—	80,732
Net loss	—	—	—	—	(61,850)	(61,850)
Cumulative effect of new accounting standard	—	—	—	—	737	737
Foreign currency translation adjustments	—	—	—	(84)	—	(84)
Unrealized loss on marketable securities	—	—	—	(2)	—	(2)
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
Restricted stock awards issued, net of cancellations	916	—	—	—	—	—
Shares issued under stock-based compensation plans	5	—	21	—	—	21
Net loss	—	—	—	—	(50,500)	(50,500)
Reimbursement of offering costs	—	—	40	—	—	40
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

Table of Contents

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years ended December 31,		
	2018	2017	2016
Operating activities:			
Net loss	$(50,500)	$(61,850)	$(50,601)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,088	5,317	3,916
Net amortization/(accretion) of premiums/discounts on investments	(142)	(39)	89
Gain on sale of investment in preferred stock	—	—	(9)
Amortization of deferred debt issuance costs	938	1,132	388
Stock-based compensation	11,697	12,170	9,236
Provision for bad debt	23	14	13
Non-cash inventory adjustments	1,426	1,323	134
Other non-cash adjustments	15	(224)	145
Changes in operating assets and liabilities:			
Accounts receivable	(878)	(1,555)	(2,250)
Inventories	(2,414)	(10,512)	(3,450)
Prepaid expenses and other assets	854	(599)	(613)
Accounts payable	(1,389)	2,557	4,105
Accrued compensation	1,059	(263)	2,172
Other current and non-current liabilities	(289)	(893)	1,088
Net cash used in operating activities	(32,512)	(53,422)	(35,637)
Investing activities:			
Payments for intellectual property licenses	—	(500)	(1,500)
Purchases of property and equipment	(2,575)	(4,815)	(7,000)
Purchases of marketable securities	(29,778)	(70,989)	(33,688)
Proceeds from sales of marketable securities	—	13,896	8,015
Maturities of marketable securities	66,300	37,500	10,050
Net cash provided by (used in) investing activities	33,947	(24,908)	(24,123)
Financing activities:			
Proceeds from issuance of common stock	1,061	87,267	30,920
Costs incurred in conjunction with public offering	—	(5,469)	(1,143)
Principal repayment of borrowings	(92)	(7,848)	(40)
Proceeds from borrowings	7,098	15,000	10,000
Costs associated with debt issuance	(20)	(187)	(90)
Proceeds from stock option exercises	22	287	712
Net cash provided by financing activities	8,069	89,050	40,359
Effect of exchange rate changes on cash	28	75	(25)
Net increase (decrease) in cash and cash equivalents	9,532	10,795	(19,426)
Cash and cash equivalents at beginning of year	27,512	16,717	36,143
Cash and cash equivalents at end of year	$37,044	$27,512	$16,717
Non-cash investing and financing activities:			
Transfer of systems from property and equipment into inventory	$1,689	$4,885	$263
Property and equipment costs incurred but not paid included in accounts payable	$372	$227	$1,159
Supplemental cash flow information:			
Cash paid for interest	$2,028	$1,643	$1,130
Cash paid for income taxes, net	$165	$61	$65

See accompanying Notes to Consolidated Financial Statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and basis of presentation

Organization

GenMark Diagnostics, Inc., the Company or GenMark, was formed by Osmetech plc, or Osmetech, as a Delaware corporation in February 2010, and had no operations prior to its initial public offering, or the IPO, which was completed in June 2010. Immediately prior to the closing of the IPO, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization, accounted for in a manner similar to a pooling-of-interests, under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of (i) the issuance of common stock of GenMark to the former shareholders of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure. The liquidation of Osmetech was completed in the fourth quarter of 2013.

The Company 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, collectively referred to as the XT-8 system. The Company sells its products in the U.S. and Europe directly and through distributors.

Basis of Presentation and Principles of Consolidation

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

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $466,883,000 at December 31, 2018. Management expects operating losses to continue through the foreseeable future. The Company's ability to transition to attaining 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. Cash, cash equivalents, and marketable securities at December 31, 2018 totaled $45,168,000. The Company has prepared cash flow forecasts which indicate, based on the Company’s current cash resources available, that the Company will have sufficient resources to fund its business for at least the next 12 months from the date of this filing.

Segment Reporting

The Company currently operates as one operating segment. Operating segments are defined as components of an enterprise for which separate financial information is evaluated regularly by the chief operating decision maker, who is the chief executive officer, in deciding how to allocate resources and assessing performance. The Company’s business operates in one operating segment because the Company’s chief operating decision maker evaluates the Company’s financial information and resources and assesses the performance of these resources on a consolidated basis. Since the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

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, intangible assets, employee-related compensation accruals, warranty liabilities, tax valuation accounts and stock-based compensation. Actual results could differ from those estimates.

Table of Contents

2. Summary of Significant Accounting Policies and Significant Accounts

Cash and 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. Marketable securities consist of certificates of deposits that mature in greater than three months. Marketable securities are accounted for as "available-for-sale" with the carrying amounts reported in the balance sheets stated at cost, which approximates their fair market value, with unrealized gains and losses, if any, reported as a separate component of stockholders' equity and included in comprehensive loss.

Restricted Cash
Restricted cash represents amounts designated for uses other than current operations and includes $758,000 as of December 31, 2018 held as security for the Company’s letter of credit with Banc of California.

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 consist of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. The allowance for doubtful accounts is determined based on an assessment of the collectability of specific customer accounts, the aging of accounts receivable, and a reserve for unknown items based upon the Company’s historical experience.

The allowance for doubtful accounts as of December 31, 2018 and 2017, comprised the following (in thousands):

	Allowance for doubtful accounts
Balance at December 31, 2016	$ 2,740
Provision for doubtful accounts	14
Balance at December 31, 2017	$ 2,754
Provision for doubtful accounts	23
Write off of uncollectible accounts	(2,702)
Balance at December 31, 2018	$ 75

The Company included $2,702,000 in the allowance for doubtful accounts as of December 31, 2017 and 2016 for past due amounts from its former customer, Natural Molecular Testing Corporation (NMTC). The fully reserved amounts

due from NMTC were written off during the year ended December 31, 2018.

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.

Table of Contents

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:

Plant and Machinery	3 – 5 years
Instruments	4 – 5 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, or 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 capital lease criteria is capitalized, and the net present value of the related lease payments is recorded as a liability. Amortization for assets noted as capital leases is recorded using the straight-line method over the shorter of the estimated useful lives or the lease terms.

Intangible Assets
Intangible assets are comprised 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 10 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 expenses.

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 charges during the years ended December 31, 2018, 2017, and 2016.

Revenue Recognition
The Company recognizes revenue from operations through the sale of products and other services. Product revenue is comprised of the sale of consumables and instruments.

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.

Table of Contents

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

The Company allocates the 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 presents disaggregated revenue by source (in thousands):

	Year ended December 31,		
	2018	2017	2016
Revenue Source:			
ePlex product revenue	$37,901	$10,172	$1,478
XT-8 product revenue	32,580	42,088	47,436
Total product revenue	70,481	52,260	48,914
License and other revenue	278	259	360
Total revenue	$70,759	$52,519	$49,274

In the years ended December 31, 2018, 2017 and 2016, Laboratory Corporation of America, Inc. represented 16%, 20% , and 27%, respectively, of the Company's total revenue.

The Company incurs incremental costs to obtain customer contracts including commissions and bonuses. The Company capitalizes the incremental costs to obtain customer contracts, which are amortized using the straight-line method over the contract term. The Company reported capitalized contract acquisition costs of $1,055,000 as of December 31, 2018 and amortization expense of $567,000 for the year ended December 31, 2018.

Product Warranties

The Company generally offers a one-year warranty for its instruments sold to customers and up to a sixty-day warranty for reagents and provides for the estimated cost of the product warranty at the time the system sale is recognized. 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 warranty repair. The Company periodically assesses and if necessary adjusts the adequacy of the warranty reserve.

Product warranty reserve activity for the years ended December 31, 2018, 2017 and 2016 is as follows (in thousands):

	2018	2017	2016
Beginning balance	$470	$219	$118
Warranty expenses incurred	(1,495)	(1,160)	(421)
Provisions	1,355	1,411	522
Ending balance	$330	$470	$219

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.

50

Table of Contents

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.

Stock-Based Compensation

The Company recognizes stock-based compensation expense related to stock options, shares purchased under the Company's 2013 Employee Stock Purchase Plan, or ESPP, restricted stock awards, restricted stock units, and market-based stock units granted to 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 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.

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.

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 comprehensive loss in the consolidated statement of stockholders' equity.

Foreign currency translation impacts recorded in accumulated other comprehensive loss (gain) for the years ended December 31, 2018, 2017, and 2016 were $44,000, $(84,000), and $77,000, respectively.

Revenue and expenses are translated at weighted average exchange rates during the applicable period. Transactions in foreign currencies were recognized using the rate of exchange prevailing at the date of the transaction. Foreign exchange gains (losses), which are included in the accompanying consolidated statements of operations, totaled $(196,000), $225,000, and $169,000 for the years ended December 31, 2018, 2017 and 2016, respectively, and relate primarily to transactions denominated in Euros.

Table of Contents

Net Loss per Common Share

Basic net loss per share is calculated by dividing loss available to stockholders of our 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, 2018, 2017 and 2016 did not include the effects of the following stock options or other unvested equity awards which were outstanding as of the end of each year because the inclusion of these securities would have been anti-dilutive (in thousands).

	Year Ended December 31,		
	2018	2017	2016
Options outstanding to purchase common stock	2,440	2,490	2,570
Other unvested equity awards	2,994	2,307	2,000
Total	5,434	4,797	4,570

Concentration of Risk

Financial instruments which potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investment securities, and accounts receivable. We limit our exposure to credit loss by placing our cash with high credit quality financial institutions. We have established guidelines relative to diversification of our cash and investment securities and their maturities that are intended to secure safety and liquidity. The following table summarizes customers who accounted for 10% or more of net accounts receivable:

	December 31,	
	2018	2017
Laboratory Corporation of America, Inc.	24 %	23 %

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 losses, unrealized gains and losses on available for sale securities, and foreign currency translation.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that the Company adopts as of the specified effective date.

In June 2018, the FASB issued Accounting Standards Update, or ASU 2018-07, Compensation - Stock Compensation (Topic 718), which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year), with early adoption permitted. The Company adopted the new standard in the second quarter of 2018 and determined that the application of the new standard did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU, 2016-18, Statement of Cash Flows (Topic 230) Restricted Cash, which requires amounts generally described as restricted cash and restricted cash equivalents to be included in the cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 (including interim periods within those periods) using a retrospective transition method for each period presented, with early adoption permitted. The Company adopted the new standard in the first quarter of 2018 using the retrospective transition method resulting in an increase in the beginning and ending cash balance of $758,000.

Table of Contents

In February 2016, the FASB issued ASU 2016-02, Leases, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new guidance requires lessees to recognize lease liabilities and corresponding right of use assets for all leases with lease terms of greater than 12 months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new guidance must be adopted using the modified retrospective approach and will be effective for the Company starting in the first quarter of 2019, with early adoption permitted. The Company will adopt ASU 2016-02 beginning on January 1, 2019 and will recognize an operating lease liability and operating right-of-use asset in its consolidated balance sheet. The standard will not have a material impact on the Company's finance leases. The Company will no longer present deferred rent in its consolidated balance sheet as it is considered a component of the operating right-of-use asset. The Company will add additional disclosures to its consolidated financial statements surrounding the remaining term and discount rate of its operating leases.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), an updated standard on revenue recognition. The new standard provides enhancements to the quality and consistency of how revenue is reported under the principle that revenue should be recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the transfer of promised goods or services. The Company adopted the new standard using the modified retrospective transition method. The cumulative effect of applying the new standard as of January 1, 2018 resulted in a net increase in opening retained earnings of $737,000 to capitalize certain costs to obtain sales contracts. The Company recognized $567,000 in expense related to the amortization of capitalized contract costs during the year ended December 31, 2018. Aside from this adjustment to beginning retained earnings and the related amortization of expense during the year ended December 31, 2018, the application of this standard did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2018.

3. Intangible Assets, net

Intangible assets as of December 31, 2018 and 2017 comprised the following (in thousands):

	December 31, 2018			December 31, 2017		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$4,750	$ (2,727)	$ 2,023	$4,750	$ (2,126)	$ 2,624

In July 2012, the Company entered into a development collaboration and license agreement with Advanced Liquid Logic, Inc., or ALL, which was acquired by Illumina, Inc. in July 2013. Under the terms of the agreement, the Company established a collaborative program to develop in-vitro diagnostic products incorporating ALL’s proprietary electrowetting technology in conjunction with the Company’s electrochemical detection technology. The Company paid ALL an upfront license payment of $250,000 and agreed to pay up to $1,750,000 in potential additional milestone payments. In June 2017, the Company satisfied the final commercial milestone under this agreement requiring the payment of $500,000, which was recorded as licensed intellectual property.

Intellectual property licenses had a weighted average remaining amortization period of 3.43 years as of December 31, 2018. Amortization expense for intangible assets amounted to $601,000, $546,000, and $406,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

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

Years Ending December 31,	Future Amortization

	Expense
2019	$ 591
2020	591
2021	591
2022	250
Total	$ 2,023

4. Stockholders' Equity

Table of Contents

On June 13, 2017, the Company entered into an Underwriting Agreement, or the Underwriting Agreement, with J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated acting as joint book-running managers and as representatives of the underwriters, or the Underwriters, relating to the issuance and sale of 6,382,978 shares of the Company's common stock, or the Offering. The price to the public in the Underwriting Agreement was $11.75 per share, before underwriting discounts and commissions. Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 957,446 shares of common stock pursuant to the Offering.

The Offering was completed on June 19, 2017, pursuant to which the Company sold a total of 7,340,424 shares of its common stock for gross proceeds of $86,250,000. The Company incurred $5,520,000 in related transaction costs, comprising underwriting discounts and commissions of $5,175,000 paid in accordance with the Underwriting Agreement, and approximately $345,000 in additional miscellaneous offering expenses.

In June 2016, the Company entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity Inc., as sales agent, or Canaccord, pursuant to which the Company could, at its discretion, offer and sell, from time to time, through Canaccord shares of its common stock having an aggregate offering price of up to $30,000,000. Under the Distribution Agreement, Canaccord could sell shares by any method deemed to be an “at-the-market” offering as defined in Rule 415 under the Securities Act or any other method permitted by law, including in privately negotiated transactions.

The Company began sales under the Distribution Agreement in August 2016 pursuant to an effective shelf registration statement on Form S-3 previously filed with the SEC. During the three months ended September 30, 2016, the Company sold 3.3 million shares of common stock, at an average per share price of $9.04, for aggregate gross proceeds of $30,000,000. The Company incurred $1,143,000 in related transaction costs, comprising commissions paid to Canaccord of 3.0% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement, or $900,000, and $243,000 in additional miscellaneous expenses.

5. Stock-Based Compensation

In 2010, the Company adopted the 2010 Equity Incentive Plan, or the 2010 Plan, which provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, restricted stock units, restricted stock bonuses and other stock-based awards. Employee participation in the 2010 Plan is at the discretion of the Compensation Committee of the Board of Directors of the Company. As of December 31, 2018, there were 539,902 shares available for future grant of awards under the 2010 Plan.

The Company estimates potential forfeitures of stock-based award grants and adjusts compensation cost recorded accordingly. The estimate of forfeitures is based on historical forfeiture experience and is adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of evaluation and will also impact the amount of stock compensation expense to be recognized in future periods.

Stock Options

All stock options granted under the 2010 Plan are exercisable at a price equal to the closing quoted market price of the Company’s shares on the NASDAQ Global Market on the date of grant and vest over a period of 4 years. Stock options are generally exercisable for a period up to 10 years after grant and are forfeited if employment is terminated before the options vest.

The following table summarizes stock option activity during the year ended December 31, 2018:

	Number of	Weighted

	shares	average exercise price
Outstanding at December 31, 2017	2,490,465	$ 9.59
Granted	—	$ —
Exercised	(5,042)	$ 4.33
Canceled	(45,509)	$ 11.35
Outstanding at December 31, 2018	2,439,914	$ 9.57
Vested and expected to vest at December 31, 2018	2,439,607	$ 9.57
Exercisable at December 31, 2018	2,416,389	$ 9.54

Table of Contents

No stock options were granted in the years ended December 31, 2018 and 2017. Stock options that were exercisable as of December 31, 2018 had a remaining weighted average contractual term of 3.82 years and an aggregate intrinsic value of $290,000. As of December 31, 2018, there was $75,000 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 0.16 years. The intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $6,700, $173,000 and $184,000, respectively. As of December 31, 2018, there were 2,439,914 stock options outstanding, which had a remaining weighted average contractual term of 3.84 years and an aggregate intrinsic value of $290,300.

The Company uses the Black-Scholes option pricing model to estimate the fair value on the applicable grant date. The assumptions used in the valuation of stock options granted in the years ended December 31, 2018, 2017 and 2016, are summarized in the following table:

	Years Ended December 31,			
	2018	2017	2016	
Expected volatility	~~%~~	~~%~~	51	%
Expected life (years)	—	—	5.90	
Risk free rate	~~%~~	~~%~~	1.35	%
Expected dividend yield	~~%~~	~~%~~	—	%

Restricted Stock Awards and Units

In March 2013, the Company transitioned to granting restricted stock units under the 2010 Plan in lieu of granting restricted stock awards. The remaining restricted stock awards vested during the year ended December 31, 2017 and all remaining expense for restricted stock awards granted by the Company was recognized during the year ended December 31, 2017. Restricted stock awards or units may be granted at the discretion of the Compensation Committee of the Board of Directors under the 2010 Plan in connection with the hiring or retention of personnel and are subject to certain conditions. 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, 2018 was as follows:

	Restricted Stock Units	
	Number of shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	2,073,440	$ 9.14
Granted	1,827,626	$ 4.55
Vested	(953,156)	$ 9.30
Canceled	(282,202)	$ 7.33
Unvested at December 31, 2018	2,665,708	$ 6.12

As of December 31, 2018, there was $11,098,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 2.46 years. The total fair value of restricted stock units that vested during the years ended December 31, 2018, 2017 and 2016 was $5,404,000, $7,813,000 and $3,192,000, respectively.

Market-Based and Performance Stock Units

The Company issued market-based stock units in February 2018, 2017 and 2016, which may result in the recipient receiving shares of stock equal to up to 200% of the target number of units granted. The vesting and issuance of Company stock subject to the 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. As of December 31, 2018, there was $1,283,000 of unrecognized stock-based compensation expense related to these awards, which is expected to be recognized over a weighted average period of 1.58 years. The total fair value of market-stock units that vested during the years ended December 31, 2018, 2017, and 2016 was $645,000, $0, and $2,433,000, respectively.

Table of Contents

The Company's market-based stock unit activity for the year ended December 31, 2018 was as follows:

	Market-Based Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	233,743	$ 10.88
Units granted	320,000	$ 7.19
Vested	(108,320)	$ 7.19
Canceled	(116,684)	$ 6.58
Unvested at December 31, 2018	328,739	$ 10.03

The fair value of these market-based stock units was estimated on the date of grant using the Monte Carlo Simulation Valuation Model, which estimates the potential outcome of achieving the market condition based on simulated future stock prices, with the following assumptions:

	Years Ended December 31,		
	2018	2017	2016
Expected volatility	65 %	54 %	49 %
Risk-free interest rate	2.40 %	1.50 %	0.90 %
Expected dividend	— %	— %	— %
Weighted average fair value	$7.19	$13.82	$4.94

The Company granted 43,200 performance-based restricted stock units in March 2014 with a grant date fair value of $12.30 per share. The vesting and issuance of Company stock pursuant to these awards depended on obtaining regulatory clearance of a designated number of ePlex products within a defined time. Stock-based compensation expense for performance-based awards is recognized when it is probable that the applicable performance criteria will be satisfied. The probability of achieving the relevant performance criteria is evaluated on a quarterly basis. On December 31, 2014, 10,800 shares of Company stock were earned and vested pursuant to outstanding performance-based restricted stock units with a total fair value of $147,000. On each of December 31, 2017, 2016, and 2015, 10,800 units were forfeited and canceled as the related performance metrics were not achieved by such dates. No performance-based restricted stock units were outstanding as of December 31, 2017 and all compensation related to the performance-based restricted stock units had been recognized.

Employee Stock Purchase Plan

The Company's stockholders originally approved the ESPP in May 2013 at the Company's Annual Meeting of Stockholders. 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 to 1,750,000.

The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the 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 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, 2018, there were 940,493 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. As a result, stock-based compensation expense related to the ESPP has been recorded during the year ended December 31, 2018.

A summary of ESPP activity for the years ended December 31, 2018, 2017, and 2016 is as follows (in thousands, except share and per share data):

	Years Ended December 31,		
	2018	2017	2016
Shares issued	252,623	174,723	138,058
Weighted average fair value of shares issued	$ 4.20	$ 5.82	$ 6.67
Employee purchases	$ 1,061	$ 1,016	$ 921

Table of Contents

The Company uses the Black-Scholes model to estimate the fair value on the date of grant for ESPP purchase rights. The assumptions used in the valuation for the years ended December 31, 2018, 2017 and 2016, are summarized in the following table:

	Years Ended December 31,		
	2018	2017	2016
Expected volatility	73% - 54%	90% - 36%	69% - 52%
Expected life (years)	0.50	0.50	0.50
Risk free rate	2.6% - 2.1%	1.5% - 0.6%	0.6% - 0.4%
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,		
	2018	2017	2016
Cost of revenue	$871	$546	$258
Sales and marketing	5,549	2,819	2,329
Research and development	2,470	3,039	2,482
General and administrative	2,807	5,766	4,167
Total stock-based compensation expense	$11,697	$12,170	$9,236

No stock-based compensation was capitalized during the periods presented, and there was no unrecognized tax benefit related to stock-based compensation for the years ended December 31, 2018, 2017 and 2016, respectively.

6. Income Taxes

The Company's income (loss) before provision (benefit) for income taxes for the years ended December 31, 2018, 2017, and 2016, respectively, was generated in the following jurisdictions (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Domestic	$(50,938)	$(62,495)	$(50,651)
Foreign	577	746	150
Total loss before income taxes	$(50,361)	$(61,749)	$(50,501)

The components of income tax expense (benefit) were as follows for the years ended December 31, 2018, 2017, and 2016, respectively (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Current expense (benefit):			
U.S. Federal	$4	$(1)	$11
State	43	22	35
Foreign	99	80	51
Total current expense	146	101	97
Deferred expense (benefit):			
U.S. Federal	(5)	—	2
State	(2)	—	1
Total deferred expense	(7)	—	3

Provision for income taxes	$139	$101	$100

Table of Contents

The components of net deferred income taxes consisted of the following at December 31, 2018 and 2017, respectively (in thousands):

	As of December 31,	
	2018	2017
Deferred income tax assets:		
NOL and credit carryforwards	$75,063	$64,486
Compensation accruals	4,542	4,143
Accruals and reserves	1,401	2,207
State tax provision	7	5
Inventory adjustments	1,193	1,329
Intangible assets	498	455
Other	620	65
Gross deferred tax assets	83,324	72,690
Less: valuation allowance	(81,964)	(71,464)
Total deferred tax assets	1,360	1,226
Deferred income tax liabilities:		
Depreciation	1,102	1,226
Contract acquisition costs	258	—
Total deferred tax liabilities	1,360	1,226
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, 2018, 2017, and 2016, respectively, as follows:

	Years Ended December 31,		
	2018	2017	2016
U.S. Federal statutory income tax rate	21.0 %	34.0 %	34.0 %
Permanent differences	(0.2)%	(0.2)%	(0.3)%
State taxes	3.0 %	2.8 %	2.3 %
Executive compensation limitation	(0.5)%	(0.5)%	(0.1)%
Tax reform	0.1 %	(59.0)%	— %
Stock-based compensation	(2.6)%	1.4 %	(3.5)%
Other	0.1 %	0.2 %	(0.4)%
Valuation allowance	(21.2)%	21.1 %	(32.2)%
Total tax provision	(0.3)%	(0.2)%	(0.2)%

The Company had federal net operating loss (NOL) carryforwards available of approximately $306,800,000 as of December 31, 2018 after consideration of limitations under Section 382 of the Internal Revenue Code, or Section 382, as further described below. The net loss generated in 2018 of $42,200,000 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 $215,000,000 as of December 31, 2018. These federal and state NOLs may be used to offset future taxable income and will begin to expire in 2025 and 2019, respectively.

The Company adopted ASU 2016-09 in the first quarter of 2017. Under the new guidance, companies will no longer record excess tax benefits and certain tax deficiencies related to share-based payments to employees in additional paid-in capital. Instead, all income tax effects of awards will be recognized in the income statement when awards vest or are settled. All excess tax benefits not previously recognized were to be recorded to retained earnings as a

cumulative effect adjustment upon adoption. Upon adoption, no adjustment to retained earnings was necessary due to the Company's valuation allowance position. Approximately $1,976,000 attributable to excess tax benefits on stock compensation that had not been previously recognized was added to the deferred tax asset for NOLs with a corresponding increase to the valuation allowance.

Table of Contents

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% or more of the Company's common stock. An assessment of such ownership changes under Section 382 was completed through December 31, 2018. As a result of this assessment, the Company determined that it experienced multiple ownership changes through 2018 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, 2018. 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, 2018, a valuation allowance of $81,964,000 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 Tax Cuts and Jobs Act, or the Jobs Act, was enacted on December 22, 2017 and introduced significant changes to U.S. income tax law. Effective in 2018, the Jobs Act reduced the U.S. federal corporate tax rate from 34% to 21%, required companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, and created new taxes on certain foreign sourced earnings. Due to the timing of the enactment and the complexity involved in applying the provisions of the Jobs Act, the Company applied the guidance in SEC Staff Accounting Bulletin (SAB) 118 by making reasonable estimates of the effects of the Jobs Act and recording provisional amounts in the consolidated financial statements as of December 31, 2017, March 31, 2018, June 30, 2018, and September 30, 2018. We have completed our accounting for the tax effects of the Jobs Act and recorded adjustments to the provisional amounts previously recorded. As of December 31, 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future, by recording a provisional expense of $36,400,000, which was fully offset by a corresponding decrease in the valuation allowance. Upon further analysis of certain aspects of the Jobs Act and refinement of our calculations during the year ended December 31, 2018, we determined that an adjustment of $(56,374) was necessary to our provisional amount for the remeasurement of deferred tax assets and liabilities, which was fully offset by a corresponding increase in the valuation allowance. The one-time transition tax is based on the total post-1986 earnings and profits (E&P) previously deferred from U.S. income taxes. In aggregate, the Company has a deficit in post-1986 E&P from its foreign subsidiaries resulting in no increase in income tax expense as a result of the transition tax. No amounts have been provided for any additional outside basis difference inherent in these entities, as these amounts continue to be indefinitely reinvested in foreign operations. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income (GILTI), states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. Because we were evaluating the provision of GILTI as of December 31, 2017, we recorded no GILTI-related deferred amounts in 2017. After further consideration in the current year, we have elected to account for GILTI in the year the tax is incurred.

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% 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, 2018, 2017 and 2016.

At December 31, 2018 and December 31, 2017, 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.

Table of Contents

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, 2018, the Company's tax years from 2012 through 2013 are 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 five years after the year for which the tax return is due or the tax is assessed.

7. Commitments and Contingencies

Leases

The Company has lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged were $1,808,000, $1,654,000 and $1,871,000 for the years ended December 31, 2018, 2017, and 2016, respectively. Pursuant to the Company's lease agreements, a portion of the monthly rent has been deferred. The balance deferred at December 31, 2018 and 2017 was $3,516,000 and $3,652,000, respectively.

In July 2018, the Company entered into an amendment to the existing lease for its corporate headquarters, which extended the term of the lease by an additional four years through June 2025. Base rent adjusts periodically throughout the extended term of this lease with monthly lease payments ranging from $107,000 to $117,000. In connection with entering into this lease amendment, the Company also received certain rent abatements during the year ended December 31, 2018.

Annual future minimum obligations for leases as of December 31, 2018 are as follows (in thousands):

Years Ending December 31,	Amount
2019	$1,989
2020	1,997
2021	2,015
2022	2,077
2023	1,939
Thereafter	2,084
Total minimum lease payments	$12,101

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.

8. Inventories

Inventory on hand as of December 31, 2018 and 2017 comprised the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$2,449	$4,534
Work-in-process	3,349	3,638
Finished goods	4,446	2,777
Total inventory	$10,244	$10,949

9. Property and Equipment, net

Property and equipment comprised the following as of December 31, 2018 and 2017 (in thousands):

Table of Contents

	December 31,	
	2018	2017
Property and equipment–at cost:		
Plant and machinery	$15,206	$13,762
Instruments	15,089	13,347
Office equipment	2,114	1,948
Leasehold improvements	10,648	10,480
Total property and equipment–at cost	43,057	39,537
Accumulated depreciation and amortization	(21,987)	(16,956)
Total property and equipment, net	$21,070	$22,581

Depreciation expense was $5,919,000, $4,771,000 and $3,510,000 for the years ended December 31, 2018, 2017 and 2016, respectively. During the years ended December 31, 2018, 2017 and 2016, the Company disposed of certain assets no longer in use with a net book value of $501,000, $207,000, and $76,000, respectively, recorded to cost of revenue, sales and marketing, research and development, or general and administrative expenses based on the asset's respective use.

10. Loan Payable

As of December 31, 2018 and 2017, long-term debt consisted of the following (in thousands):

	December 31,	
	2018	2017
Term Loans		
Term Loan A - 6.9% principal	$7,619	$10,000
Term Loan B - 6.9% principal	7,619	10,000
Term Loan C - 7.4% principal	12,000	15,000
Term Loan D - 8.8% principal	663	—
Term Loan E - 8.8% principal	7,098	—
Final fee obligation	3,288	2,429
Repayment of principal	—	(7,762)
Unamortized issuance costs	(2,245)	(1,641)
Total debt, net	36,042	28,026
Current portion of long-term debt	—	(7,927)
Long-term debt	$36,042	$20,099

Term Loans

In January 2015, the Company entered into a Loan and Security Agreement, or the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other financial institutions party thereto, as lenders, pursuant to which the Company obtained (a) up to $35,000,000 in a series of term loans and (b) a revolving loan in the maximum amount of $5,000,000. The term loans will accrue interest at a rate equal to (a) the greater of 1.00% or the 3-year treasury rate in effect at the time of funding, plus (b) an applicable margin between 4.95% and 5.90% per annum.

In September 2018, the Company amended its LSA to extend the interest-only period for amounts borrowed by the Company under the Agreement until January 1, 2020. The Company’s payments are due based upon a 24-month amortization schedule with the remaining outstanding principal and accrued interest amounts due on January 1, 2021, or the Final Maturity Date. The Company obtained additional term loans of $663,000 and $7,098,000, respectively, during the year ended December 31, 2018.

61

Table of Contents

As of December 31, 2018, the Company had borrowed all $42,762,000 under the term loans as provided in the LSA, and the Company had not borrowed any of the $5,000,000 available under the revolving loan. The Company will be required to pay a $20,000 annual management fee due on each anniversary of the closing date of the Amendment and a $3,288,000 final payment fee due on the Final Maturity Date. Interest expense recognized on the term loans for the years ended December 31, 2018, 2017, and 2016 totaled $2,018,000, $1,820,000, and $1,184,000, respectively.

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. The LSA includes customary events of default, including instances of a material adverse change in our operations, that could require immediate payment of the Company's obligations. As of December 31, 2018, the Company was in compliance with all covenants under the LSA.

Revolving Loan

Pursuant to the LSA, the Company may borrow up to $5,000,000 under the revolving loan facility. Borrowings under the revolving loan will accrue interest at a rate equal to (a) the greater of 1.25% per annum or a base rate as determined by a three-month LIBOR-based formula, plus (b) an applicable margin between 2.95% and 3.95% based on certain criteria as set forth in the LSA. All principal and interest outstanding under the revolving loan is due and payable on the Maturity Date. Following the funding of Term Loan A, the Company is required to pay a commitment fee equal to 0.75% per annum of the amounts made available but unborrowed under the revolving loan. As of December 31, 2018, the Company had not borrowed any amounts pursuant the revolving loan facility. Interest expense recognized for the unused revolving loan facility fee for the years ended December 31, 2018, 2017, and 2016 was $35,000, $35,000, and $42,000, respectively.

Debt Issuance Costs

As of December 31, 2018 and 2017, the Company had $2,245,000 and $1,641,000, respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt.

For the twelve months ended December 31, 2018, 2017, and 2016, amortization of debt issuance costs were $938,000, $1,132,000, and $298,000, respectively, which was included in interest expense in the Company's consolidated statements of comprehensive loss for the periods presented.

Letter of Credit

In September 2012, the Company provided a $758,000 letter of credit issued by Banc of California to the landlord of its executive office facility in Carlsbad, California. This letter of credit was secured with $758,000 of restricted cash as of December 31, 2018.

11. 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.

12. Other Current Liabilities

Other current liabilities as of December 31, 2018 and 2017 comprised the following (in thousands):

	December 31,	
	2018	2017
Accrued royalties	$534	$605
Accrued warranties	330	469
Deferred revenue	245	448
Deferred rent	520	593
Other accrued liabilities	1,414	1,111
Total other current liabilities	$3,043	$3,226

Table of Contents

13. Fair Value of Financial Instruments

The following table presents the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at December 31, 2018 and 2017, respectively, (in thousands):

	December 31, 2018 Quotes 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	$8,953	$ —	$ —	$8,953
Marketable securities				
Corporate notes and bonds	—	6,389	—	6,389
Commercial paper	—	2,493	—	2,493
Total	$8,953	$ 8,882	$ —	$17,835

	December 31, 2017 Quotes 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	$6,362	$ —	$ —	$6,362
Corporate notes and bonds	—	1,498	—	1,498
Marketable securities				
Corporate notes and bonds	—	26,278	—	26,278
U.S. government and agency securities	—	11,976	—	11,976
Commercial paper	—	6,982	—	6,982
Total	$6,362	$ 46,734	$ —	$53,096

At December 31, 2018, the carrying value of the financial instruments measured and classified within Level 1 was based on quoted prices and marked to market. Level 2 inputs for the valuations are limited to quoted prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability.

Table of Contents

14. Marketable Securities

The following table summarizes the Company's marketable securities at December 31, 2018 and 2017 (in thousands):

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 6,393	$ —	$ (4)	$ 6,389
U.S. government and agency securities	—	—	—	—
Commercial paper	2,493	—	—	2,493
Total marketable securities	$ 8,886	$ —	$ (4)	$ 8,882

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 26,303	$ —	$ (25)	$ 26,278
U.S. government and agency securities	11,981	—	(5)	11,976
Commercial paper	6,982	—	—	6,982
Total marketable securities	$ 45,266	$ —	$ (30)	$ 45,236

The following table summarizes the maturities of the Company's marketable securities at December 31, 2018 (in thousands):

	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 8,886	$ 8,882
Total	$ 8,886	$ 8,882

Table of Contents

15. Quarterly financial data (unaudited)

The following tables show a summary of the Company’s quarterly financial results for each of the four quarters of 2018 and 2017 (in thousands, except for per share amounts):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2018:				
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)
Earnings per share data [(1)]:				
Net loss per common share—basic and diluted	$(0.21)	$(0.30)	$(0.20)	$(0.21)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2017:				
Total revenue	$12,535	$12,359	$11,603	$16,022
Gross profit	$6,183	$4,884	$4,203	$4,735
Loss from operations	$(13,556)	$(17,267)	$(14,731)	$(13,963)
Net loss	$(13,917)	$(17,989)	$(15,408)	$(14,536)
Earnings per share data [(1)]:				
Net loss per common share—basic and diluted	$(0.30)	$(0.37)	$(0.28)	$(0.26)

(1) Basic and diluted earnings per share are computed independently for each of the quarters presented. As such, the sum of the quarterly basic and diluted earnings per share information may not equal annual basic and diluted earnings per share.

16. Subsequent Events

On February 1, 2019 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "New LSA") with Solar Capital Ltd. and certain other financial institutions (collectively, the "Lenders"). Pursuant to the New LSA, the Lenders are providing the Company with up to $65 million in a series of term loans (collectively, the "Term Loans"), of which $50 million (the "Tranche 1 Loan") was funded on the Effective Date. An additional $15 million (the "Tranche 2 Loan") is available to be funded at the Company's option, but no later than December 31, 2019, provided that the Company achieves a designated amount of product revenues on a trailing six-month basis (the "Tranche 2 Loan Funding Condition").

On the Effective Date, approximately $38.8 million of the proceeds from the Tranche 1 Loan were used by the Company to repay all outstanding principal, interest, related fees, and other obligations under the Company's existing Loan and Security Agreement with Solar Senior Capital Ltd. dated January 12, 2015 (as amended through the Effective Date), with the remaining borrowings to be used to satisfy the Company's working capital needs and for other general business purposes.

The Term Loans will 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 LIBOR 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, 2021 (the “Interest Only Period”). If (a) the Tranche 2 Loan Funding Condition is timely satisfied by the Company, (b) the Company exercises its option to borrow the Tranche 2 Loan, and

(c) the Company achieves an additional designated amount of product revenues on a trailing six-month basis on or before December 31, 2020, then the Interest Only Period may, at the Company's election, be extended for both Term Loans through February 28, 2022. Following the Interest Only Period (as the same may be extended pursuant to the terms of the New LSA), 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.

Table of Contents

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, or the 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, 2018, 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, 2018 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, 2018 based on the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO). Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Table of Contents

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, 2018, 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, 2018, 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, 2018 and 2017, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 25, 2019 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, 2019

Table of Contents

Item 9B. OTHER INFORMATION

None.

PART III.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Board of Directors Information,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” contained in the Proxy Statement to be filed in connection with our 2018 Annual Meeting of Stockholders, or the Proxy Statement.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics for our directors, officers and employees, which is available on our website at www.genmarkdx.com in the Investor Relations section under “Corporate Governance.” If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code of business conduct and ethics to any executive officer or director, we will promptly disclose, within four business days of such amendment or waiver, the nature of the amendment or waiver on our website. The information on, or that can be accessed from, our website is not incorporated by reference into this Annual Report.

Item 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Executive Compensation,” “Compensation Committee Interlocks and Insider Participation” and “Report of the Compensation Committee” contained in the Proxy Statement.

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

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” contained in the Proxy Statement.

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

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Certain Relationships and Related Transactions,” and “Board of Directors Information” contained in the Proxy Statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Principal Accountant Fees and Services” and “Report of the Audit Committee” contained in the Proxy Statement.

Table of Contents

Item 15. EXHIBITS, FINANCIAL STATEMENTS AND 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

Table of Contents

Exhibit	Description
3.1	Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
3.2	Amended and Restated By-Laws (incorporated by reference to our Current Report on 8-K filed on August 2, 2018).
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 (File No. 333-165562) 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	Amended and Restated Chemically Modified Enzymes Kit Patent License Agreement by and between Roche Molecular Systems, Inc., F. Hoffman-La Roche Ltd., and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 27, 2008 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 21, 2010). †
10.8	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). †
10.9	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). †
10.10	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). †

10.11	Loan and Security Agreement dated as of January 12, 2015 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, General Electric Capital Corporation, and certain other financial institutions as lenders (incorporated by reference herein to our Form 10-Q filed with the SEC on May 5, 2015). †
10.12	Amendment to Loan and Security Agreement dated September 30, 2015 by and among GenMark Diagnostics, Inc., as borrower, General Electric Capital Corporation, as agent and lender, and the lenders signatory thereto (incorporated by reference herein to our Form 10-Q filed with the SEC on October 27, 2015). †
10.13	Letter agreement dated March 17, 2016 by and among GenMark Diagnostics, Inc., as borrower, Healthcare Financial Solutions, LLC, as agent and lender, and the lenders signatory thereto (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 3, 2016). †
10.14	First Amendment to Loan and Security Agreement dated July 27, 2016 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on November 3, 2016). †
10.15	Second Amendment to Loan and Security Agreement dated as of February 27, 2017 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 2, 2017).

Table of Contents

Exhibit	Description
10.16	Third Amendment to Loan and Security Agreement dated as of May 31, 2017 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on August 1, 2017).
10.17	Fourth Amendment to Loan and Security Agreement dated as of June 7, 2017 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on August 1, 2017).
10.18	Fifth Amendment to Loan and Security Agreement dated as of December 13, 2017 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-K as filed with the SEC on February 27, 2018) †
10.19	Sixth Amendment to Loan and Security Agreement dated as of September 28, 2018 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on October 29, 2018). †
10.20	Seventh Amendment to Loan and Security Agreement dated as of November 29, 2018 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions as lenders. + ü
10.21	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).
10.22	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). *
10.23	The GenMark Diagnostics, Inc. 2017 Bonus Plan (incorporated by reference herein from our Form 8-K as filed with the SEC on February 24, 2017). *
10.24	The GenMark Diagnostics, Inc. 2018 Bonus Plan (incorporated by reference herein from our Form 8-K as filed with the SEC on March 1, 2018). *
10.25	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). *
10.26	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). *
10.27	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010). *

10.28	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). *
10.29	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). *
10.30	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). *
10.31	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). *
10.32	Executive Employment Agreement, dated as of April 5, 2011, 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 13, 2011). *
10.33	Employment Offer Letter effective May 7, 2014 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 May 12, 2014). *

Table of Contents

Exhibit	Description
10.34	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). *
10.35	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). *
10.3	Underwriting Agreement, dated June 13, 2017, by and among GenMark Diagnostics, Inc., J.P. Morgan Securities LLC and Merrill Lynch, Pierce, Fenner & Smith (incorporated by reference to our Current Report on Form 8-K filed with the SEC on June 14, 2017).
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 pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. ü
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. ü
32.1	Certification of the principal executive officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350. ü
32.2	Certification of the principal financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350. ü
101	XBRL Instance Document
101	XBRL Taxonomy Extension Schema Document
101	XBRL Taxonomy Calculation Document
101	XBRL Taxonomy Definition Linkbase Document
101	XBRL Taxonomy Label Linkbase Document
101	XBRL Taxonomy Presentation Linkbase Document

---

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

ü Included in this filing.
† Confidential treatment has been granted with respect to certain portions of this exhibit.
+ GenMark has requested confidential treatment with respect to certain portions of this exhibit.

Item 16. FORM 10-K SUMMARY

None.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 25, 2019.

GENMARK DIAGNOSTICS, INC.

By: /s/ HANY MASSARANY
Name: Hany Massarany
Title: Chief Executive Officer, President and Director (principal executive officer)

February 25, 2019

By: /s/ Johnny Ek
Name: Johnny Ek
Title: Chief Financial Officer (principal financial and accounting officer)

February 25, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hany Massarany 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/ HANY MASSARANY Hany Massarany	President, Chief Executive Officer and Director (principal executive officer)	2/25/2019
/S/ JOHNNY EK Johnny Ek	Chief Financial Officer (principal financial and accounting officer)	2/25/2019
/S/ JAMES FOX James Fox	Chairman of the Board	2/25/2019
/S/ DARYL J. FAULKNER Daryl J. Faulkner	Director	2/25/2019

/S/ KEVIN C. O'BOYLE Kevin C. O'Boyle	Director	2/25/2019
/S/ MICHAEL S. KAGNOFF Michael S. Kagnoff	Director	2/25/2019
/s/ LISA M. GILES Lisa M. Giles	Director	2/25/2019