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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the year ended December 31, 2019

☐ **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:	**Trading Symbol**	**Name of Each Exchange on which Registered:**
Common Stock, par value $0.0001 per share	**GNMK**	**The NASDAQ Stock Market LLC**

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

Large accelerated filer	☐	Accelerated filer	x
Non-accelerated filer	☐	Smaller reporting company	x
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, 2019, 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 $348,230,000 based on the closing sale price for the registrant's common stock on the NASDAQ Global Market on that date of $6.49 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 27, 2020 was 60,775,873. 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.

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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," "expect," "target," "anticipate," "aim," "plan" and similar expressions, including their use in the negative, are intended to identify forward-looking statements.

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

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

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

Trademarks and Trade Names

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

PART I.

Item 1. BUSINESS

GenMark Diagnostics, Inc., 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 have also received 510(k) market clearance from the FDA for our ePlex Blood Culture Identification Gram-Positive (BCID-GP) Panel, Blood Culture Identification Fungal Pathogen (BCID-FP) Panel, and Blood Culture Identification Gram-Negative (BCID-GN) Panel. We are developing our ePlex Gastrointestinal Pathogen (GI) Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional molecular 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, 2019, 2018, and 2017 were approximately $47.4 million, $50.5 million, and $61.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of $514.2 million. Our operations to date have been funded principally through sales of capital stock, borrowings, and cash from operations. We expect to incur increasing expenses over the next several years, principally to further expand our diagnostic test panel menu for our ePlex instrument, as well as to further increase our manufacturing capabilities and commercial organization.

Our Strategy

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

- ***Drive Commercialization of our ePlex System***. We believe our ePlex system is an attractive solution for a broad range of hospitals and laboratories that need rapid, actionable identification of infectious pathogens as well as those hospitals and laboratories that may lack the technical or economic resources to perform molecular diagnostic testing with existing products and technology. We believe the ePlex system will expand our current potential user base from approximately 1,000 domestic customers to approximately 12,000 potential customers globally.
- ***Expand our Menu of Clinical Diagnostic Products.*** We intend to develop a broad menu of molecular diagnostic tests for our ePlex instrument that we believe will satisfy important medical needs and present attractive commercial opportunities. We are developing our ePlex GI Panel for the detection of pathogens associated with gastrointestinal infections. In addition, we are actively evaluating the development of additional panels that we believe will meet important, unmet clinical needs.

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

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.

Our Technology

Our eSensor Technology

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

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

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

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

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

Digital Microfluidics

Digital microfluidics is another innovative technology included within our ePlex system which we have exclusively licensed within a defined field of use from an affiliate of Illumina, Inc. Digital microfluidics is a technique for moving small droplets of liquid using electrowetting, a process for making a surface hydrophobic or hydrophilic based on the application of a voltage to a surface. Our ePlex printed circuit board contains eSensor electrodes capable of nucleic acid detection along with electrowetting electrodes capable of digital microfluidics. The ePlex system uses numerous choreographed digital inputs to perform the fluid manipulations associated with sample-to-answer molecular diagnostics. Drops are dispensed, mixed, merged, heated, cooled, split and delivered, all under precise and programmable digital control. In this manner, standard procedures of the molecular diagnostics lab (e.g., DNA purification, PCR, exonuclease digestion, etc.) can be performed automatically within our ePlex cartridge.

Our Instrument Systems

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

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

Market Opportunity

We believe the aggregate global total addressable market for the tests we currently offer, are actively developing on ePlex, or may consider developing is approximately $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.

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 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, we continue to make investments in these customer facing organizations.

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

- ***Reagent Rental:*** A reagent rental agreement generally provides that a customer commits to purchase a minimum number of test cartridges over the term of the agreement, and a portion of the charge for each cartridge is attributable to a usage fee for the instrument.

- ***Capital Purchase:*** The instrument is paid for upfront and in its entirety by the customer. Customers are also eligible to receive structured pricing incentives if they enter into an optional annual minimum cartridge purchase commitment.

Customers

Our target customers include hospital-based and reference laboratories, as well as research institutions. We believe our ePlex system will expand our current potential user base from approximately 1,000 domestic customers to approximately 12,000 potential customers globally. In 2019, 2018, and 2017, Laboratory Corporation of America, Inc. represented 14%, 16% and 20%, respectively, of our total revenue.

Competition

We primarily face competition in the molecular diagnostic testing markets with testing products and systems developed by public and private companies such as bioMerieux (which acquired Biofire Diagnostics, Inc.), Luminex Corporation (which acquired Nanosphere, Inc.), Danaher Corporation (which acquired Cepheid), Qiagen (which acquired Stat-Dx), Siemens (which acquired Fast Track Diagnostics), T2 BioSystems, Accelerate Diagnostics, Hologic, Inc., Seegene, Mobidiag, Qvella, Curetis, Bosch/Randox, aprimeo diagnostics, Roche Diagnostics, and Abbott Molecular Diagnostics. Our diagnostic tests also face competition with laboratory developed tests (LDTs) developed by national and regional reference laboratories and hospitals. We believe that our testing systems compete largely on the basis of accuracy, reliability, enhanced laboratory workflow, multiplex capability, ease-of-use, turnaround time, customer service and support, patient safety, and return on investment for customers.

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

Intellectual Property

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

We believe that our patent portfolio, which includes over 100 owned and exclusively licensed U.S. and foreign patents and approximately 25 pending applications, and other intellectual property rights provide us with extensive protection of our eSensor systems. We continue to pursue the issuance of new patents to protect our ongoing research, development, and commercial activities, in particular with respect to our ePlex system and related consumables. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2039. Our success depends to a significant degree upon our ability to police infringement and continue to develop proprietary products and technologies without infringing the intellectual property rights of others.

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

We also have filed for registration, or obtained registration, in the U.S. and other countries for marks used with our products and technology. Our issued trademarks in the United States and/or Europe include GenMark®, GenMark DX®, eSensor®, 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 medical device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA. We have obtained 510(k) market clearance from the FDA for the following molecular diagnostic tests for use on our XT-8 system: the Respiratory Viral Panel, the eSensor Warfarin Sensitivity Test, the Cystic Fibrosis Genotyping Test, and the Thrombophilia Risk Test. We have also obtained 510(k) market clearance from the FDA for our ePlex instrument, as well as our ePlex RP, BCID-GP, BCID-GN, and BCID-FP Panels.

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 event 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.

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

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

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

Foreign Government Regulation. We intend to market our products in European and other international markets. The regulatory pre-market requirements for *in vitro* diagnostic, 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, physicians, and other health care providers and require significant public disclosure concerning permitted arrangements. These laws are vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. We must operate our business within the requirements of these laws and, if we were accused of violating them, we could be forced to expend significant resources on investigation, remediation, and monetary penalties.

Patient Protection and Affordable Care Act

Our operations are affected by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the Health Care Act. The Health Care Act 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, 2019, we had 437 employees, of which: 87 employees were involved in research and development; 250 were involved in operations, manufacturing, and quality assurance; 66 were involved in sales and marketing; and 34 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 influenza outbreaks in the Northern hemisphere. However, historical seasonal patterns should not be considered reliable indicators of our future net sales or financial performance.

Corporate and Available Information

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

We make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, 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.

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, among other attributes. However, the commercial success of ePlex will depend on a number of factors, including, but not limited to:

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

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

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

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

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

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

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

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

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

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

Our diagnostic test panels also face competition from LDTs developed by national and regional reference laboratories and hospitals. LDTs may not currently be subject to the same regulatory requirements, including those requiring clinical studies and FDA review and clearance or approval that may apply to our diagnostic products.

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

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

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

Some hospital-based and reference laboratories may not consider adopting our instrument systems unless we offer a broader menu of diagnostic test panels or may choose not to convert from competitive products. In addition, in order to commercialize our products, we are required to undertake time consuming and costly development activities, including clinical studies for which the outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to effectively compete, our revenues and our ability to achieve profitability will be significantly impaired.

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

We have obtained CE Mark for our ePlex Instrument and the following ePlex assays: the ePlex RP Panel, the ePlex BCID-GP Panel, the ePlex BCID-GN Panel, and the ePlex BCID-FP Panel. We are commercializing our ePlex system internationally via a network of distribution partners, which is augmented by a limited set of direct sales and technical support personnel 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. We also must comply with applicable foreign regulatory agency post-market requirements, including routine Notified Body conformity assessments to quality system standards (e.g. ISO 13485). Any failure to maintain post-market compliance with foreign regulatory requirements could harm our business, operations, and/or financial condition.

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

Our ability to sell our products depends in part on the extent to which reimbursement related to performing tests using our products is available from governmental authorities, such as Medicare and other domestic and foreign governmental programs, private insurance plans, managed care organizations, and other organizations. There are ongoing efforts by governmental and third party-payors to contain or reduce the costs of healthcare coverage. For example, a number of Medicare Administrative Contractors (MACs) recently issued final local coverage determinations limiting or eliminating Medicare coverage for the use of certain multiplex molecular respiratory tests such as our ePlex RP 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. Furthermore, if our competitors are able to obtain product-specific reimbursement levels higher than those for our similarly situated products, or if the scope of coverage applicable to our competitors' products exceeds the scope of coverage applicable to our products, the overall demand for our products or the prices at which we are able to sell our products may be negatively impacted.

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

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

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 or the quality of subcomponents, equipment, and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results or product development goals within the time frame we expect, or at all.

Finding solutions to product quality, reliability, variability, and raw material sourcing issues is time consuming and expensive, and we may incur significant additional costs or lose revenue as a result of, among other things, delayed product introduction, product recalls, shipment holds, scrapped material, manufacturing delays 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 suppliers have a sole source supply for certain key products, product components, ancillary items, and raw materials used to run our tests. If we are unable to satisfy our forecasted demand from existing suppliers for our products, or we or our suppliers are unable to find alternative suppliers for key product components, ancillary items or raw materials at reasonably comparable prices, it could have a material adverse effect on our financial condition and results of operations. Additionally, although we have entered into supply agreements with most of our suppliers of strategic reagents and parts to help ensure component availability and flexible purchasing terms with respect to the purchase of such components, if our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable, cost-effective alternative on reasonable terms, or at all, which could limit our ability to manufacture our products.

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

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

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;
- the potential obsolescence and/or inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;

- the inability to qualify alternate sources without impacting performance claims of our products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers;
- the imposition of tariffs on certain product components based on our suppliers' location;
- the potential for financial hardship or other detrimental circumstances at key suppliers that may impact our ability to source key materials or services required for the manufacturing of our products; and
- increases in prices of raw materials and key components.

The manufacturing operations for our test panel cartridges use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly and time consuming to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facilities or the facilities of any of our key suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, 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. We outsource the manufacture of our ePlex instrument to Plexus, which specializes in the manufacturing of electronic and electro-mechanical devices. We currently maintain an inventory of XT-8 instruments and related components to satisfy the expected demand for our XT-8 system for the foreseeable future, as well as to service XT-8 instruments installed at customer locations. While we work closely with Plexus to ensure continuity of supply while maintaining high quality and reliability, and we believe our current stock of XT-8 instruments and related components will be sufficient for our and our customers’ anticipated needs, we cannot guarantee that these efforts will be successful.

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

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

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

Until such time, if ever, as we can generate positive cash flows from operations, we will be required to finance our operations with our cash resources and amounts made available under our credit facility and pursuant to our ongoing at-the-market (ATM) equity offering. 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 within the Northern hemisphere. New information or the introduction of advanced treatment options with respect to a particular disease may also affect the rate of related diagnostic testing. Although certain infectious disease outbreaks tend to occur each year, the timing, severity, and length of these incidents varies from one year to another and can vary across different patient populations. In addition, we may not accurately predict the impact of new therapies on disease prevalence or changes to infectious disease testing recommendations affecting our products. As a result of one or more of these factors, we may not be able to accurately forecast sales from our infectious disease products.

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

Our largest customer, Laboratory Corporation of America, Inc., accounted for approximately 14% and 16% of our total revenue for the fiscal years ended December 31, 2019 and 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 panels;
- the expenses we incur to increase our manufacturing capabilities, including expenses to purchase capital equipment and increase our manufacturing capacity and yield;
- the expenses we incur for research and development required to maintain and improve our technology, including developing new ePlex test menu;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including product marketing, sales, and distribution expenses;
- the expenses we incur in licensing technologies or securing rights to new products from third parties to expand the menu of products and services we plan to offer;
- our sales strategy and whether the revenues from sales of our test cartridges or systems will be sufficient to offset our expenses;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

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

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

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

commercial launch of new ePlex molecular diagnostic tests in the United States. We may be unsuccessful in obtaining FDA clearance for our expanding ePlex test menu within our expected time frame, or at all, which could adversely impact our future financial performance and cause our stock price to decline.

The regulatory environment is constantly evolving. For example, the FDA conducted a review of the pre-market clearance process in response to internal and external concerns regarding the 510(k) program and, in January 2011, announced 25 action items designed to make the process more rigorous and transparent. Some of these proposals, if enacted, could impose additional regulatory requirements for device manufacturers which could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances. Similarly, the European Union, 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. Specifically, the IVDR repeals and replaces the IVDD. Unlike the directive, which must be implemented into the national laws of the European Economic Area, or EEA, Member States, the IVD regulation is directly applicable in all EEA Member States and is intended to eliminate current differences in regulation of IVDs among EEA Member States. Under the IVDR, the 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 routine Notified Body conformity assessments to quality system standards (e.g., ISO 13485). Any failure to maintain post-market compliance with FDA or foreign regulatory requirements could harm our business, operations, and/or financial condition.

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

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

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

The False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. We have implemented procedures designed to ensure our compliance with relevant legal requirements. Nevertheless, if our marketing, sales, or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

The Health Care Act also imposes reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. In February 2013, the Centers for Medicare and Medicaid Services, 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.

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 retail devices purchased by the general public for individual use. There is no exemption for small companies, and we paid the tax from 2013 through 2015. Recently, Congress and the administration have proposed and taken various steps to revise, repeal, or delay implementation of various aspects of PPACA. If the PPACA is significantly revised, repealed, or if implementation of various aspects are delayed, such modification, repeal, or delay may impact our business, financial condition, results of operations, cash flows, and the trading price of our securities. Complying with PPACA may significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

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

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

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

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

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

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

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

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

We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that compete with our products. Currently, our patent portfolio is comprised on a worldwide basis of more than 100 owned and exclusively licensed patents and approximately 25 additional pending patent applications. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2039. However, not all of the pending or future patent applications owned by or licensed to us are guaranteed to mature into patents, and, moreover, issued patents owned by or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

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

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

Our manufacturing processes and facilities and those of some of our contract manufacturers must comply with QSR and certain foreign regulatory requirements, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of our devices. The FDA and other foreign regulatory bodies enforce the QSR and similar foreign regulatory requirements through periodic announced and/or unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies.

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

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

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

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

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

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

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 $47.4 million, $50.5 million and $61.9 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $514.2 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.

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.

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, 2019, we had pre-2018 net operating loss, or NOL, carryforwards available of approximately $264.6 million for U.S. federal income tax purposes. The federal NOL carryforwards generated prior to 2018 will begin to expire in 2025. The NOL generated in 2018 and 2019 of $78,190,000 will carry forward indefinitely and be available to offset up to 80% of future taxable income each year.

Section 382 of the U.S. Internal Revenue Code of 1986, as amended, 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 $249.7 million as of December 31, 2019. We have recorded a full valuation allowance against our net deferred tax assets.

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.

Item 3. LEGAL PROCEEDINGS

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

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

Market Information

Our common stock has been quoted on The NASDAQ Global Market under the symbol "GNMK" since May 28, 2010.

Stockholders

The last reported sale price of our common stock on February 27, 2020 as reported on the NASDAQ Global Market was $3.62. As of February 27, 2020, there were 817 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.

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, 2019, 2018, and 2017 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2019 and 2018 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, 2016 and 2015 and the selected consolidated balance sheet data as of December 31, 2017, 2016, and 2015 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.

FIVE YEAR SELECTED FINANCIAL DATA

	Years ended December 31,				
	2019	2018	2017	2016	2015
Consolidated Statements of Comprehensive Loss Data:	(In thousands, except per share data)				
Revenue					
Product revenue	$ 87,491	$ 70,481	$ 52,260	$ 48,914	$ 39,029
License and other revenue	530	278	259	360	382
Total revenue	88,021	70,759	52,519	49,274	39,411
Cost of revenue	59,418	51,278	32,514	19,700	15,317
Gross profit	28,603	19,481	20,005	29,574	24,094
Operating expenses:					
Sales and marketing	24,118	21,777	20,557	14,734	14,385
General and administrative	19,159	17,545	16,205	14,363	13,772
Research and development	27,140	27,931	42,760	49,458	37,472
Total operating expenses	70,417	67,253	79,522	78,555	65,629
Loss from operations	(41,814)	(47,772)	(59,517)	(48,981)	(41,535)
Other income (expense):					
Interest income	512	711	561	176	125
Interest expense	(5,961)	(3,108)	(3,042)	(1,536)	(880)
Other (expense) income	(23)	(192)	249	(160)	133
Total other expense	(5,472)	(2,589)	(2,232)	(1,520)	(622)
Loss before provision for income taxes	(47,286)	(50,361)	(61,749)	(50,501)	(42,157)
Income tax expense	64	139	101	100	40
Net loss	$ (47,350)	$ (50,500)	$ (61,850)	$ (50,601)	$ (42,197)
Net loss per share, basic and diluted	$ (0.82)	$ (0.91)	$ (1.21)	$ (1.15)	$ (1.00)
Weighted average number of shares outstanding basic and diluted	57,603	55,669	51,169	44,100	42,157

	As of December 31,				
	2019	2018	2017	2016	2015
Consolidated Balance Sheet Data:	(In thousands)				
Cash and cash equivalents and marketable securities [1][2][3]	$ 53,460	$ 45,168	$ 71,990	$ 41,566	$ 45,465
Total assets	111,473	92,981	122,299	80,324	70,667
Long-term liabilities	74,994	39,147	23,399	15,752	11,481
Total liabilities	99,310	59,434	51,142	42,173	22,070
Accumulated deficit	(514,233)	(466,883)	(416,383)	(355,270)	(304,669)
Total stockholders' equity [1][2][3]	12,163	33,547	71,157	38,151	48,597

(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.

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

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, 2019, 2018, and 2017 were approximately $47.4 million, $50.5 million, and $61.9 million, respectively. As of December 31, 2019, we had an accumulated deficit of $514.2 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 Products and Technology

We offer our ePlex sample-to-answer instrument and RP Panel, BCID-GP Panel, BCID-GN Panel, and BCID-FP Panel for sale in the United States and internationally. We are also developing our ePlex GI Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

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

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

Sales and Marketing Expenses

Sales and marketing expenses include costs associated with our direct sales force, sales management, marketing, 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.

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

We recognize revenue from operations through the sale of our 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 we expect 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 jurisdictions. Employee sales commissions are recorded as sales and marketing expenses when incurred or amortized over the estimated contract term when resulting from new contract acquisition efforts.

Inventory

We value inventories at the lower of cost or net realizable value on a part-by-part basis and provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover, assumptions about future demand for our products, and market conditions. We determine excess and obsolete inventories based on an estimate of the future demand for our products within a specified time horizon, which is generally 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.

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

Recent Accounting Pronouncements

For a summary of recent accounting pronouncements applicable to our consolidated financial statements, see Note 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, 2019, 2018 and 2017 (tables in thousands):

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Revenue	$ 88,021	$ 70,759	52,519	$ 17,262	24%	$ 18,240	35%

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 $17.3 million, or 24%, when comparing the years ended December 31, 2019 and 2018, primarily driven by growth in ePlex product revenue which features a higher selling price than our XT-8 system due to the additional technology and features of its sample-to-answer capabilities. For the year ended December 31, 2019, ePlex product revenue increased by $22.4 million, or 59%, to $60.3 million due to new customers adopting the ePlex system for respiratory and blood stream infection testing. ePlex product revenue represented 69% of total product revenue during the year ended December 31, 2019. XT-8 revenue decreased by $5.4 million to $27.2 million during the year ended December 31, 2019, primarily due to XT-8 customers that converted in 2018 to our ePlex system for respiratory testing.

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. For the year ended December 31, 2018, ePlex product revenue increased by $27.7 million, or 273%, 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 product revenue represented 54% of total 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.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Cost of Revenue	$ 59,418	$ 51,278	$ 32,514	$ 8,140	16%	$ 18,764	58 %
Gross Profit	$ 28,603	$ 19,481	$ 20,005	$ 9,122	47%	$ (524)	(3)%
Gross Margin	32.5%	27.5%	38.1%				

The increase in cost of revenue for the year ended December 31, 2019, when compared to the prior year, is primarily a result of the growth in ePlex product revenue. ePlex revenue increased by 59% when compared to the prior year and represented 68% of total revenue during the period. The increase in ePlex sales resulted in increased standard product costs of $12.5 million over the prior year as ePlex products carry higher cost profiles due to the enhanced technology and features as compared to XT-8 and corresponding higher average selling prices. Other cost of revenue increased due to increases of $1.1 million in inventory reserves expense and $774 thousand from increased royalties expense resulting from higher product revenue.

Gross profit increased by $9.1 million, or a gross margin increase of 5 percentage points during the year ended December 31, 2019, when compared to the prior year driven entirely by improvements to ePlex gross margin. These increases are the result of continued production gains in the manufacture of ePlex consumables. The increase in gross margin to 32.5% was attributable to decreased costs of $5.8 million due to improved overhead cost absorption and the realization of manufacturing efficiencies and $574 thousand from decreased warranty and customer and product technical support expenses.

The increase in cost of revenue for the year ended December 31, 2018, when compared to the prior year, is primarily a result of the composition of our revenue with ePlex product revenue increasing by 273% versus the prior year and representing 54% of total revenue during the period. Standard product costs increased by $19.1 million when comparing the year ended December 31, 2018 to the prior year as a result of increased sales volumes. Cost of revenue also increased due to increases of $411 thousand due to higher freight and royalty expense and $335 thousand from increased inventory reserves expense.

Gross margin and gross profit decreased during the year ended December 31, 2018, when compared to the prior year, due to the growth in ePlex product revenue relative to XT-8. The ePlex system carries a higher cost profile due to its enhanced technology and features relative to XT-8 and its early product life cycle. Total Company gross margin represented 27.5% of total revenue for the year ended December 31, 2018 and gross profit decreased by $524 thousand, when compared to the prior year. The decrease in gross margin and gross profit due to the shift in product mix was partially offset by an $866 thousand decrease in warranty and customer and product technical support and $364 thousand from improved overhead cost absorption and the realization of manufacturing efficiencies.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Sales and Marketing	$ 24,118	$ 21,777	$ 20,557	$ 2,341	11%	$ 1,220	6%

The increase in sales and marketing expense for the year ended December 31, 2019, when compared to the prior year, was primarily driven by increases of $1.5 million in personnel expense, $613 thousand in evaluation kits expense resulting from new ePlex system evaluations, and $251 thousand in higher allocated facility and information technology expense resulting from increased headcount.

The increase in sales and marketing expense for the year ended December 31, 2018, when compared to the prior year, was primarily related to increases of $493 thousand in evaluation kits expense resulting from new ePlex system evaluations, $307 thousand in depreciation expense associated with ePlex systems under evaluation at customer locations, $125 thousand in personnel expense, and $135 thousand in supplies expense due to auxiliary equipment provided to customers.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
General and Administrative	$ 19,159	$ 17,545	$ 16,205	$ 1,614	9%	$ 1,340	8%

The increase in general and administrative expense for the year ended December 31, 2019, when compared to the prior year, was primarily related to increases of $1.1 million in personnel expense, including $786 thousand in stock-based compensation expense, and $535 thousand in higher facility and information technology expense.

The increase in general and administrative expense for the year ended December 31, 2018, when compared to the prior year, was primarily related to increases in professional service expense of $729 thousand primarily due to public company responsibilities and personnel expense of $662 thousand due to higher employee bonuses.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Research and Development	$ 27,140	$ 27,931	$ 42,760	$ (791)	(3)%	$ (14,829)	(35)%

The decrease in research and development expense for the year ended December 31, 2019, when compared to the prior year, was primarily driven by a decrease of $1.5 million in clinical study expense based upon the timing of the completed ePlex BCID clinical studies, which was partially offset by a $718 thousand increase in prototype materials used by our assay development teams.

The decrease in research and development expense for the year ended December 31, 2018, when compared to the prior year, 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 personnel expense due to decreased headcount. These decreases were 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.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Total Other Expense	$ (5,472)	$ (2,589)	$ (2,232)	$ (2,883)	111%	$ (357)	16%

Other 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 expense for the year ended December 31, 2019, when compared to the prior year, was primarily due to an increase in interest expense of $2.9 million on amounts due under our debt facility.

The change in other expense for the year ended December 31, 2018, when compared to the prior year, 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.

	Years ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Income Tax Expense	$ 64	$ 139	$ 101	$ (75)	(54)%	$ 38	38%

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. The decrease in income tax expense for the year ended December 31, 2019, when compared to the prior year, was primarily driven by a decrease in international income taxes. Income taxes remained consistent when comparing the years ended December 31, 2018 and 2017.

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, 2019, we had $59.1 million of working capital, including $53.5 million in cash, cash equivalents, and marketable securities.

Cash Flows

The following table shows cash flow information for the years ended December 31, 2019, 2018 and 2017:

	Years Ended December 31,		
	2019	2018	2017
Cash used in operating activities	$ (34,926)	$ (32,512)	$ (53,422)
Cash (used in) provided by investing activities	(2,172)	33,947	(24,908)
Cash provided by financing activities	45,173	8,069	89,050
Effect of exchange rate changes on cash	(1)	28	75
Net increase in cash and cash equivalents	$ 8,074	$ 9,532	$ 10,795

Cash flows used in operating activities

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

Net cash used in operating activities decreased by $20.9 million for the year ended December 31, 2018, when compared to the prior year. The decrease in cash used in operating activities was primarily due to an $11.4 million decrease in net loss, an $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 deferred debt issuance costs.

Cash flows (used in) provided by investing activities

Net cash used in investing activities increased by $36.1 million for the year ended December 31, 2019, when compared to the prior year. The increase in net cash used in investing activities was primarily due to a decrease of $34.2 million in the maturities of marketable securities. The increase in net cash used in investing activities was also attributable to increases of $2.4 million in purchases of marketable securities and $483 thousand in purchases of property, plant, and equipment.

Net cash provided by investing activities increased by $58.9 million for the year ended December 31, 2018, when 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.

Cash flows provided by financing activities

Net cash provided by financing activities increased by $37.1 million for the year ended December 31, 2019, when compared to the prior year. The increase in cash provided by financing activities was primarily due to increases of $24.3 million in net proceeds from borrowings under our debt facility, $12.5 million in net proceeds from the sale of our common stock, and $435 thousand in proceeds from stock option exercises.

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

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

- the level of revenues and the rate of our revenue growth;
- 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

On February 1, 2019, or the Effective Date, we entered into a Loan and Security Agreement, or the LSA, with Solar Capital Ltd. and certain other financial institutions, or, collectively, the Lenders. Pursuant to the LSA and certain subsequent amendments, the Lenders are providing us with up to $70 million in a series of term loans, of which $50 million was funded on the Effective Date. An additional $20 million was funded on December 16, 2019 upon our achievement of a designated amount of product revenues on a trailing six-month basis.

The term loans under the LSA 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 Intercontinental Exchange Benchmark Administration, Ltd. rate then in effect as of the applicable payment date, plus (b) 5.90% per annum. We are only required to make interest payments on amounts borrowed pursuant to the term loans from the applicable funding date until February 28, 2021, or the Interest Only Period. If we achieve a designated amount of product revenues on a trailing six-month basis on or before March 31, 2020, then the Interest Only Period can be extended through February 28, 2022. Following the Interest Only Period, monthly installments of principal and interest under the term loans will be due until the original principal amount and applicable interest is fully repaid by February 1, 2023.

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

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

Equity Distribution Agreement

On August 5, 2019, we entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity LLC, or Canaccord, pursuant to which we may offer and sell, from time to time, shares of our common stock having an aggregate offering price of up to $35 million. Under the Distribution Agreement, Canaccord may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. We are not obligated to sell any shares under the Distribution Agreement. Canaccord is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement. During the year ended December 31, 2019, we sold 2.3 million shares of common stock under the Equity Distribution Agreement at a weighted average price per share of $5.77 resulting in aggregate gross proceeds of $13.1 million. We incurred $574 thousand in related transaction costs, comprising commissions paid to Canaccord of $392 thousand, as well as $182 thousand in additional miscellaneous expenses.

Letter of Credit

In September 2012, we provided a $758 thousand 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 thousand of restricted cash at December 31, 2019.

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, 2019, 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]	$ 10,112	$ 1,997	$ 4,092	$ 3,322	$ 701
Supplier payment obligations [2]	20,220	5,704	10,039	4,477	—
Debt obligations [3]	86,610	5,871	73,637	7,102	—
Total obligations	$ 116,942	$ 13,572	$ 87,768	$ 14,901	$ 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) We enter into supplier contracts in the ordinary course of our business. Certain supplier agreements require us to purchase minimum quantities of goods or services on an annual basis.

(3) Our contractual obligation under its LSA consists of principal payments, interest, and fees due to the 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 thousand 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.

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, 2019, based on current interest rates and our total debt outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of GenMark Diagnostics, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 March 2, 2020 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
March 2, 2020

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

	As of December 31,	
	2019	**2018**
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 44,360	$ 36,286
Short-term marketable securities	9,100	8,882
Accounts receivable, net of allowances of $376 and $75, respectively	16,759	11,534
Inventories	11,301	10,244
Prepaid expenses and other current assets	1,877	1,483
Total current assets	83,397	68,429
Property and equipment, net	20,419	21,070
Intangible assets, net	1,432	2,023
Restricted cash	758	758
Noncurrent operating lease right-of-use assets	4,642	—
Other long-term assets	825	701
Total assets	$ 111,473	$ 92,981
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 12,249	$ 9,886
Accrued compensation	7,493	7,358
Current operating lease liability	1,842	—
Other current liabilities	2,732	3,043
Total current liabilities	24,316	20,287
Deferred rent	—	2,996
Long-term debt	69,145	36,042
Noncurrent operating lease liability	5,796	—
Other noncurrent liabilities	53	109
Total liabilities	99,310	59,434
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; 60,255 and 56,240 shares issued and outstanding as of December 31, 2019 and 2018, respectively	6	6
Additional paid-in capital	526,294	500,344
Accumulated deficit	(514,233)	(466,883)
Accumulated other comprehensive income	96	80
Total stockholders’ equity	12,163	33,547
Total liabilities and stockholders’ equity	$ 111,473	$ 92,981

See accompanying Notes to Consolidated Financial Statements.

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

	Years ended December 31,		
	2019	**2018**	**2017**
Revenue			
Product revenue	$ 87,491	$ 70,481	$ 52,260
License and other revenue	530	278	259
Total revenue	88,021	70,759	52,519
Cost of revenue	59,418	51,278	32,514
Gross profit	28,603	19,481	20,005
Operating expenses:			
Sales and marketing	24,118	21,777	20,557
General and administrative	19,159	17,545	16,205
Research and development	27,140	27,931	42,760
Total operating expenses	70,417	67,253	79,522
Loss from operations	(41,814)	(47,772)	(59,517)
Other income (expense):			
Interest income	512	711	561
Interest expense	(5,961)	(3,108)	(3,042)
Other (expense) income	(23)	(192)	249
Total other expense	(5,472)	(2,589)	(2,232)
Loss before provision for income taxes	(47,286)	(50,361)	(61,749)
Income tax expense	64	139	101
Net loss	$ (47,350)	$ (50,500)	$ (61,850)
Net loss per share, basic and diluted	$ (0.82)	$ (0.91)	$ (1.21)
Weighted average number of shares outstanding basic and diluted	57,603	55,669	51,169
Other comprehensive loss			
Net loss	$ (47,350)	$ (50,500)	$ (61,850)
Other comprehensive income (loss):			
Foreign currency translation adjustments, net of tax	11	44	(84)
Net unrealized gains (losses) on marketable securities, net of tax	5	27	(2)
Total other comprehensive income (loss)	16	71	(86)
Total comprehensive loss	$ (47,334)	$ (50,429)	$ (61,936)

See accompanying Notes to Consolidated Financial Statements.

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, 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 loss on marketable securities	—	—	—	27	—	27
Balance—December 31, 2018	56,240	6	500,344	80	(466,883)	33,547
Stock-based compensation expense	—	—	12,046	—	—	12,046
Issuance of employee stock purchase plan shares	210	—	962	—	—	962
Restricted stock awards issued, net of cancellations	1,461	—	—	—	—	—
Shares issued under stock-based compensation plans	81	—	457	—	—	457
Issuance of common stock, net of offering expenses	2,263	—	12,485	—	—	12,485
Net loss	—	—	—	—	(47,350)	(47,350)
Foreign currency translation adjustments	—	—	—	11	—	11
Unrealized gain on marketable securities	—	—	—	5	—	5
Balance—December 31, 2019	60,255	$ 6	$ 526,294	$ 96	$ (514,233)	$ 12,163

See accompanying Notes to Consolidated Financial Statements.

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

	Years ended December 31,		
	2019	**2018**	**2017**
Operating activities:			
Net loss	$ (47,350)	$ (50,500)	$ (61,850)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7,268	7,088	5,317
Net accretion of premiums/discounts on investments	(133)	(142)	(39)
Amortization of deferred debt issuance costs	1,740	938	1,132
Stock-based compensation	12,046	11,697	12,170
Provision for bad debt	338	23	14
Non-cash inventory adjustments	2,631	1,426	1,323
Other non-cash adjustments	537	15	(224)
Changes in operating assets and liabilities:			
Accounts receivable	(5,584)	(878)	(1,555)
Inventories	(6,534)	(2,414)	(10,512)
Prepaid expenses and other assets	(750)	854	(599)
Accounts payable	1,501	(1,389)	2,557
Accrued compensation	(885)	1,059	(263)
Other current and non-current liabilities	249	(289)	(893)
Net cash used in operating activities	(34,926)	(32,512)	(53,422)
Investing activities:			
Payments for intellectual property licenses	—	—	(500)
Purchases of property and equipment	(2,092)	(2,575)	(4,815)
Purchases of marketable securities	(32,135)	(29,778)	(70,989)
Proceeds from sales of marketable securities	—	—	13,896
Maturities of marketable securities	32,055	66,300	37,500
Net cash (used in) provided by investing activities	(2,172)	33,947	(24,908)
Financing activities:			
Proceeds from issuance of common stock	14,021	1,061	87,267
Costs incurred in conjunction with public offering	(574)	—	(5,469)
Principal repayment of borrowings	(35,093)	(92)	(7,848)
Proceeds from borrowings	70,000	7,098	15,000
Costs associated with debt issuance	(3,638)	(20)	(187)
Proceeds from stock option exercises	457	22	287
Net cash provided by financing activities	45,173	8,069	89,050
Effect of exchange rate changes on cash	(1)	28	75
Net increase in cash and cash equivalents	8,074	9,532	10,795
Cash and cash equivalents at beginning of year	37,044	27,512	16,717
Cash and cash equivalents at end of year	$ 45,118	$ 37,044	$ 27,512
Non-cash investing and financing activities:			
Transfer of systems from inventory to property and equipment	$ 2,846	$ 1,689	$ 4,885
Property and equipment costs incurred but not paid included in accounts payable	$ 1,234	$ 372	$ 227
Supplemental cash flow information:			
Cash paid for interest	$ 3,946	$ 2,028	$ 1,643
Cash paid for income taxes, net	$ 155	$ 165	$ 61

See accompanying Notes to Consolidated Financial Statements.

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 directly to customers in the U.S. and internationally primarily via a network of distribution partners.

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 $514,233,000 at December 31, 2019. 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, 2019 totaled $53,460,000. 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.

In June 2019, the Company changed its estimate of the forfeiture rate used to determine stock-based compensation expense based upon recent employment history. The change in forfeiture rate resulted in an additional $174,000 in stock-based compensation expense.

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, 2019 held as security for the Company’s letter of credit with Banc of California.

The following table shows a reconciliation of the Company's cash and cash equivalents in the consolidated balance sheet to cash, cash equivalents, and restricted cash in the consolidated statement of cash flows as of December 31, 2019 and 2018:

	December 31,		
	2019	**2018**	**2017**
Cash and cash equivalents	$ 44,360	$ 36,286	$ 26,754
Restricted cash	758	758	758
Total cash, cash equivalents, and restricted cash	45,118	37,044	27,512

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, 2019 and 2018, comprised the following (in thousands):

	Allowance for doubtful accounts
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
Provision for doubtful accounts	338
Write off of uncollectible accounts	(37)
Balance at December 31, 2019	$ 376

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.

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

Intangible Assets

Intangible assets 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 expense.

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, including intangible assets, by periodically evaluating the carrying value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If impairment is indicated, the Company writes down the carrying value of the asset to its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows. The Company did not recognize any impairment charges during the years ended December 31, 2019, 2018, and 2017.

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

Revenue is recorded net of discounts, and sales taxes collected on behalf of governmental authorities. Employee sales commissions are recorded as 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,		
	2019	**2018**	**2017**
ePlex product revenue	$ 60,268	$ 37,901	$ 10,172
XT-8 product revenue	27,223	32,580	42,088
Total product revenue	87,491	70,481	52,260
License and other revenue	530	278	259
Total revenue	$ 88,021	$ 70,759	$ 52,519

In the years ended December 31, 2019, 2018 and 2017, Laboratory Corporation of America, Inc. represented 14%, 16%, and 20%, 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 $1,340,000 and $1,055,000 as of December 31, 2019 and 2018 and amortization expense of $733,000 and $567,000 for the years ended December 31, 2019 and 2018, respectively.

Product Warranties

The Company generally offers a one-year warranty for its instruments sold to customers and up to a sixty-day warranty for consumables 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 most recent three years is as follows (in thousands):

	Year ended December 31,		
	2019	2018	2017
Beginning balance	$ 330	$ 470	$ 219
Warranty expenses incurred	(1,326)	(1,495)	(1,160)
Provisions	1,275	1,355	1,411
Ending balance	$ 279	$ 330	$ 470

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.

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 units, and market-based stock units granted to employees, non-employees, and directors in exchange for services. The compensation expense is based on the fair value of the applicable award utilizing various assumptions regarding the underlying attributes of the award. The stock-based compensation expense is recorded in cost of revenues, sales and marketing, research and development, and/or general and administrative expenses based on the employee's respective function.

The estimated fair value of stock granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense that approximates straight-line expense to reflect vesting as it occurs. The 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 (income) for the years ended December 31, 2019, 2018, and 2017 were $11,000, $44,000, and $(84,000), 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 $(25,000), $(196,000), and $225,000 for the years ended December 31, 2019, 2018 and 2017, respectively, and relate primarily to transactions denominated in Euros.

Net Loss per Common Share

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

The calculations of diluted net loss per share for the years ended December 31, 2019, 2018 and 2017 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,		
	2019	**2018**	**2017**
Options outstanding to purchase common stock	2,037	2,440	2,490
Other unvested equity awards	3,124	2,994	2,307
Total	5,161	5,434	4,797

Concentration of Risk

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

	December 31,	
	2019	**2018**
Company A [(1)]	24%	24%
Company B [(2)]	11%	(2)

(1) Company A is a clinical laboratory network with worldwide operations.
(2) Company B is an integrated delivery network with domestic operations. Company B's outstanding accounts receivable was below 10% of the Company's net accounts receivable at December 31, 2018.

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 February 2016, the FASB issued ASU 2016-02, *Leases*, which outlines a comprehensive lease accounting model and supersedes the prior lease guidance. The new guidance requires lessees to recognize lease liabilities and corresponding right-of-use, or ROU, assets for all leases with lease terms of greater than 12 months. The guidance 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 is effective for annual periods beginning after December 15, 2018. The Company adopted the new standard in the first quarter of 2019 using the package of transition practical expedients. The Company recognized non-current ROU assets of $5,097,000 and current and non-current lease liabilities of $1,780,000 and $6,832,000, respectively, upon adoption. Deferred rent is now presented as an offset to the Company's non-current operating lease ROU assets. The new lease standard did not have a material impact on the Company's consolidated statements of comprehensive loss, cash flows, or stockholders' equity.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, which introduces a new methodology for recognizing credit losses on financial instruments. The new standard requires entities to measure financial instruments at their amortized cost basis, net of an allowance for credit losses. The allowance for credit losses must reflect an entity's current estimate of all expected credit losses. The new guidance also requires entities to present credit losses on debt securities accounted for under the available-for-sale method as an allowance rather than a write down. The new guidance must be adopted through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period presented and is effective for fiscal years beginning after December 15, 2019. The Company will adopt ASU 2016-13 during the first quarter of 2020. The adoption of the new guidance is not expected to have a material impact on the Company's consolidated financial statements.

3. Intangible Assets, net

Intangible assets as of December 31, 2019 and 2018 comprised the following (in thousands):

	December 31, 2019			December 31, 2018		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$ 4,750	$ (3,318)	$ 1,432	$ 4,750	$ (2,727)	$ 2,023

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 2.44 years as of December 31, 2019. Amortization expense for intangible assets amounted to $591,000, $601,000, and $546,000 for the years ended December 31, 2019, 2018 and 2017, respectively.

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

Years Ending December 31,	Future Amortization Expense
2020	$ 591
2021	591
2022	250
Total	$ 1,432

4. Stockholders' Equity

On August 5, 2019, the Company entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity LLC, or Canaccord, pursuant to which the Company may offer and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $35,000,000. Under the Distribution Agreement, Canaccord may sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or any other method permitted by law, including in privately negotiated transactions. The Company is not obligated to sell any shares under the Distribution Agreement. Canaccord is entitled to a commission of 3% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement. During the year ended December 31, 2019, the Company sold 2,263,000 shares of common stock under the Distribution Agreement at a weighted average price per share of $5.77 resulting in aggregate gross proceeds of $13,059,000. The Company incurred $574,000 in related transaction costs, comprising commissions paid to Canaccord of $392,000, as well as $182,000 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, 2019, there were 974,236 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-based 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 ten 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, 2019:

	Number of shares		Weighted average exercise price
Outstanding at December 31, 2018	2,439,914	$	9.57
Granted	—	$	—
Exercised	(121,383)	$	5.90
Canceled	(281,399)	$	11.46
Outstanding at December 31, 2019	2,037,132	$	9.53
Vested at December 31, 2019	2,037,132	$	9.53
Exercisable at December 31, 2019	2,037,132	$	9.53

No stock options were granted during the years ended December 31, 2019 and 2018. There were 2,037,132 stock options that were outstanding and exercisable as of December 31, 2019, which had a remaining weighted average contractual term of 3.27 years and an aggregate intrinsic value of $269,000. As of December 31, 2019, the Company has recognized all compensation expense related to stock options granted under the 2010 plan. The intrinsic value of stock options exercised during the years ended December 31, 2019, 2018 and 2017 was $131,000, $6,700 and $173,000, respectively.

Restricted Stock Units

Restricted stock 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, 2019 was as follows:

	Number of shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	2,665,708	$ 6.12
Granted	1,594,151	$ 6.71
Vested	(1,311,508)	$ 6.10
Canceled	(278,852)	$ 6.78
Unvested at December 31, 2019	2,669,499	$ 6.42

As of December 31, 2019, there was $12,488,000 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, 2019, 2018 and 2017 was $8,727,000, $5,404,000 and $7,813,000, respectively.

Market-Based Stock Units

The Company issued market-based stock units in February 2019, 2018, and 2017, 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, 2019, there was $1,815,000 of unrecognized stock-based compensation expense related to these awards, which is expected to be recognized over a weighted average period of 1.73 years. The total fair value of market-based stock units that vested during the years ended December 31, 2019, 2018, and 2017 was $797,000, $645,000, and $0, respectively.

The Company's market-based stock unit activity for the year ended December 31, 2019 was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	328,739	$ 10.03
Granted	460,000	$ 10.22
Vested	(165,771)	$ 9.16
Canceled	(168,739)	$ 13.09
Unvested at December 31, 2019	454,229	$ 9.40

The fair value of market-based stock units is estimated on the grant date 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,		
	2019	2018	2017
Expected volatility	64%	65%	54%
Risk-free interest rate	2.50%	2.40%	1.50%
Expected dividend	—%	—%	—%
Weighted average fair value	$ 10.22	$ 7.19	$ 13.82

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, 2019, there were 730,916 shares of common stock available for issuance under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock-based compensation. As a result, stock-based compensation expense related to the ESPP has been recorded during the year ended December 31, 2019.

A summary of ESPP activity for the most recent three years is as follows (in thousands, except share and per share data):

	Years Ended December 31,		
	2019	2018	2017
Shares issued	209,577	252,623	174,723
Weighted average fair value of shares issued	$ 4.59	$ 4.20	$ 5.82
Employee purchases	$ 962	$ 1,061	$ 1,016

The Company uses the Black-Scholes model to estimate the fair value on the grant date for ESPP purchase rights. The assumptions used in the valuation for the years ended December 31, 2019, 2018 and 2017, are summarized in the following table:

	Years Ended December 31,		
	2019	2018	2017
Expected volatility	50% - 40%	73% - 54%	90% - 36%
Expected life (years)	0.50	0.50	0.50
Risk free rate	2.3% - 1.6%	2.6% - 2.1%	1.5% - 0.6%
Expected dividend yield	—%	—%	—%

Stock-Based Compensation Expense Recognition

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

	Years Ended December 31,		
	2019	2018	2017
Cost of revenue	$ 953	$ 871	$ 546
Sales and marketing	3,014	5,549	2,819
Research and development	1,744	2,470	3,039
General and administrative	6,335	2,807	5,766
Total stock-based compensation expense	$ 12,046	$ 11,697	$ 12,170

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, 2019, 2018 and 2017, respectively.

6. Income Taxes

The Company's income (loss) before provision for income taxes for the years ended December 31, 2019, 2018, and 2017, respectively, was generated in the following jurisdictions (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Domestic	$ (47,807)	$ (50,938)	$ (62,495)
Foreign	521	577	746
Total loss before income taxes	$ (47,286)	$ (50,361)	$ (61,749)

The components of income tax expense were as follows for the years ended December 31, 2019, 2018, and 2017, respectively (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Current expense			
U.S. Federal	$ 27	$ 4	$ (1)
State	29	43	22
Foreign	11	99	80
Total current expense	67	146	101
Deferred benefit			
U.S. Federal	(2)	(5)	—
State	(1)	(2)	—
Total deferred benefit	(3)	(7)	—
Provision for income taxes	$ 64	$ 139	$ 101

The components of net deferred income taxes consisted of the following at December 31, 2019 and 2018, respectively (in thousands):

	As of December 31,	
	2019	2018
Deferred income tax assets:		
NOL and credit carryforwards	$ 84,362	$ 75,063
Compensation accruals	4,669	4,542
Accruals and reserves	764	1,401
Operating lease liability	1,906	—
State tax provision	6	7
Inventory adjustments	881	1,193
Intangible assets	542	498
Other	2,031	620
Gross deferred tax assets	95,161	83,324
Less: valuation allowance	(92,717)	(81,964)
Total deferred tax assets	2,444	1,360
Deferred income tax liabilities:		
Depreciation	951	1,102
Contract acquisition costs	334	258
Operating lease right-of-use assets	1,159	—
Total deferred tax liabilities	2,444	1,360
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, 2019, 2018, and 2017, respectively, as follows:

	Years Ended December 31,		
	2019	2018	2017
U.S. Federal statutory income tax rate	21.0 %	21.0 %	34.0 %
Permanent differences	(0.3)%	(0.2)%	(0.2)%
State taxes	3.8 %	3.0 %	2.8 %
Executive compensation limitation	(0.9)%	(0.5)%	(0.5)%
Tax reform	— %	0.1 %	(59.0)%
Stock-based compensation	(1.2)%	(2.6)%	1.4 %
Other	0.1 %	0.1 %	0.2 %
Valuation allowance	(22.7)%	(21.2)%	21.1 %
Total tax provision	(0.2)%	(0.3)%	(0.2)%

The Company had pre-2018 federal net operating loss (NOL) carryforwards available of approximately $264,600,000 as of December 31, 2019 after consideration of limitations under Section 382 of the Internal Revenue Code, or Section 382, as further described below. The federal NOL carryforwards generated prior to 2018 will begin to expire in 2025. The NOL generated in 2018 and 2019 of $78,190,000 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 $249,700,000 as of December 31, 2019. The state NOLs may be used to offset future taxable income and have begun to expire.

The future utilization of the Company’s NOL carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of changes in ownership by stockholders that hold 5% 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, 2019. 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, 2019, a valuation allowance of $92,717,000 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 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, 2019, 2018 and 2017.

At December 31, 2019 and 2018, the Company had not accrued any interest or penalties related to uncertain tax positions. The Company does not anticipate that there will be a significant change in the amount of unrecognized tax benefits over the next twelve months. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

The Company is subject to taxation in the United States and various state and foreign jurisdictions. The Company's Federal and state tax returns since inception are subject to examination due to the carryover of net operating losses. As of

December 31, 2019, the Company's 2013 fiscal year tax return is subject to examination by the United Kingdom tax authorities. The statute of limitations for the assessment and collection of income taxes related to other foreign tax returns varies by country. In the foreign countries where the Company has operations, these time periods generally range from three to six years after the year for which the tax return is due or the tax is assessed.

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 $1,965,000, $1,808,000, and $1,654,000 for the years ended December 31, 2019, 2018, and 2017, respectively.

Pursuant to the adoption of the new lease standard, the Company reported noncurrent operating lease ROU assets of $4,642,000, and current and noncurrent operating lease liabilities of $1,842,000 and $5,796,000, respectively, as of December 31, 2019. The Company reported current and noncurrent deferred rent under the existing lease standard of $520,000 and $2,996,000, respectively, at December 31, 2018. The Company's operating lease liabilities were measured at a weighted average discount rate of 11.2% and have a weighted average remaining term of 4.97 years.

Annual future minimum obligations for leases as of December 31, 2019 are as follows (in thousands):

Years Ending December 31,	Amount
2020	$ 1,997
2021	2,015
2022	2,077
2023	1,939
2024	1,383
Thereafter	701
Total	10,112
Less: imputed interest	(2,474)
Total operating lease liabilities	$ 7,638

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, 2019 and 2018 comprised the following (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 3,408	$ 2,449
Work-in-process	3,776	3,349
Finished goods	4,117	4,446
Total inventory	$ 11,301	$ 10,244

9. Property and Equipment, net

Property and equipment comprised the following as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Property and equipment–at cost:		
Plant and machinery	$ 16,551	$ 15,206
Instruments	16,796	15,089
Office equipment	2,150	2,114
Leasehold improvements	11,896	10,648
Total property and equipment–at cost	47,393	43,057
Accumulated depreciation and amortization	(26,974)	(21,987)
Total property and equipment, net	$ 20,419	$ 21,070

Depreciation expense was $5,944,000, $5,919,000, and $4,771,000 for the years ended December 31, 2019, 2018, and 2017, respectively. During the years ended December 31, 2019, 2018, and 2017, the Company disposed of certain assets no longer in use with a net book value of $461,000, $501,000, and $207,000, 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, 2019 and 2018, long-term debt consisted of the following (in thousands):

	December 31,	
	2019	2018
Term Loans		
Term Loan A - 6.9% interest	$ —	$ 7,619
Term Loan B - 6.9% interest	—	7,619
Term Loan C - 7.4% interest	—	12,000
Term Loan D - 8.8% interest	—	663
Term Loan E - 8.8% interest	—	7,098
Term Loan - 8.4% interest	70,000	—
Final fee obligation	4,165	3,288
Unamortized issuance costs	(5,020)	(2,245)
Total debt, net	69,145	36,042
Current portion of long-term debt	—	—
Long-term debt	$ 69,145	$ 36,042

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 the LSA and certain subsequent amendments, the Company borrowed $42,762,000 in a series of term loans and had the ability to borrow against a revolving loan in the maximum amount of $5,000,000. During the term of the LSA, the term loans thereunder accrued 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. The Company borrowed all $42,762,000 under the term loans as provided in the LSA, and the Company did not borrow any of the $5,000,000 available under the revolving loan.

On February 1, 2019, or the Effective Date, the Company entered into a new 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 and certain subsequent amendments, the Lenders are providing the Company with up to $70,000,000 in a series of term loans, or, collectively, the Term Loans, of which $50,000,000, or the Tranche 1 Loan, was funded on the Effective Date. An additional $20,000,000, or the Tranche 2 Loan, was funded on December 16, 2019 upon the Company's achievement of a designated amount of product revenues on a trailing six-month basis.

On the Effective Date, approximately $38,800,000 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 LSA, with the remaining borrowings to be used to satisfy the Company's working capital needs and for other general business purposes. The Company accounted for the repayment of its obligations under the LSA as a debt modification. The Company has capitalized the issuance costs it incurred when entering into the New LSA, which are being amortized over the remaining term of the New LSA.

The Term Loans under the New LSA 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 Intercontinental Exchange Benchmark Administration Ltd. rate then in effect as of the applicable payment date, plus (b) 5.90% per annum. The Company is only required to make interest payments on amounts borrowed pursuant to the Term Loans from the applicable funding date until February 28, 2021, or the Interest Only Period. If the Company achieves a designated amount of product revenues on a trailing six-month basis on or before March 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, or the Final Maturity Date.

Under the New 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 New LSA. As of December 31, 2019, the Company was in compliance with all covenants under the New LSA.

The New LSA also contains customary events of default (subject, in certain instances, to specified cure periods), including, but not limited to, the failure to make payments of interest or premium when due, the failure to comply with certain covenants and agreements specified in the 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.

Debt Issuance Costs

As of December 31, 2019 and 2018, the Company had $5,020,000 and $2,245,000, respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt.

For the year ended December 31, 2019, 2018, and 2017, amortization of debt issuance costs were $1,740,000, $938,000, and $1,132,000, 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, 2019.

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 to certain eligible employees.

12. Other Current Liabilities

Other current liabilities as of December 31, 2019 and 2018 comprised the following (in thousands):

	December 31,	
	2019	2018
Accrued royalties	$ 882	$ 534
Accrued warranties	279	330
Deferred revenue	323	245
Deferred rent	—	520
Other accrued liabilities	1,248	1,414
Total other current liabilities	$ 2,732	$ 3,043

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, 2019 and 2018, respectively, (in thousands):

	December 31, 2019			
	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	$ 19,647	$ —	$ —	$ 19,647
Marketable securities				
Corporate notes and bonds	$ —	$ 9,100	$ —	$ 9,100
Total	$ 19,647	$ 9,100	$ —	$ 28,747

	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

At December 31, 2019, 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.

14. Marketable Securities

The following table summarizes the Company's marketable securities at December 31, 2019 and 2018 (in thousands):

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

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

The following table summarizes the maturities of the Company's marketable securities at December 31, 2019 (in thousands):

	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 9,099	$ 9,100
Total	$ 9,099	$ 9,100

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 2019 and 2018 (in thousands, except for per share amounts):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2019:				
Total revenue	$ 21,533	$ 18,374	$ 20,918	$ 27,196
Gross profit	$ 5,863	$ 6,573	$ 7,050	$ 9,117
Loss from operations	$ (10,910)	$ (11,910)	$ (10,288)	$ (8,706)
Net loss	$ (12,080)	$ (13,308)	$ (11,675)	$ (10,287)
Earnings per share data [1]				
Net loss per common share—basic and diluted	$ (0.21)	$ (0.23)	$ (0.20)	$ (0.17)

	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)

(1) Basic and diluted earnings per share are calculated 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.

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, 2019, 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, 2019 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, 2019 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, 2019.

Management’s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting
We have audited GenMark Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2019, 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, 2019, 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, 2019 and 2018, the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated March 2, 2020 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
March 2, 2020

Item 9B. OTHER INFORMATION

On February 27, 2020, we and the Lenders entered into an amendment to the LSA pursuant to which the parties agreed that, if we achieve a designated amount of product revenues on a trailing six-month basis for the period ending March 31, 2020, then we can extend the Interest Only Period through February 28, 2022.

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 2019 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.

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

Exhibit	Description
3.1	Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 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).
4.1	Description of Registrant's Securities. ü
10.1	Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 8, 2010 (incorporated by reference to our Registration Statement on Form S-1 filed with the Commission on March 19, 2010).
10.2	Settlement and Release Agreement and First Amendment to Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc., dated July 1, 2010 (incorporated by reference herein form our Form 10-K as filed with the SEC on March 14, 2013).
10.3	Settlement and Release Agreement and Second Amendment to Lease, dated January 19, 2012, by and between the Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 21, 2012).
10.4	Second Amendment to License Agreement dated June 20, 2000 by and between California Institute of Technology and Clinical Micro Sensors, Inc. (incorporated by reference herein form our Form 10-K/A as filed with the SEC on April 18, 2013). †
10.5	Third Amendment to Lease Agreement dated August 28, 2012, by and between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on November 8, 2012).
10.6	Fourth Amendment to Lease Agreement dated July 24, 2018, by and between The Campus Carlsbad LLC and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on July 30, 2018).
10.7	Non-Exclusive License Agreement by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Caliper Life Sciences Inc. dated effective as of March 27, 2012 (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 10, 2012). †
10.8	Development Collaboration and License Agreement, dated July 26, 2012, by and between Advanced Liquid Logic, Inc. and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. (incorporated by reference herein from our Form 10-Q/A as filed with the SEC on March 22, 2013). †
10.9	Amendment Number One to Development Collaboration and License Agreement, effective as of January 18, 2016, by and among Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc., Advanced Liquid Logic, Inc., and Illumina, Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 3, 2016). †
10.10	Loan and Security Agreement dated as of 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). †
10.11	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). †
10.12	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). †
10.13	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). †
10.14	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). †

Exhibit	Description
10.15	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). †
10.16	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). †
10.17	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). †
10.18	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). †
10.19	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 (incorporated by reference herein from our Form 10-K as filed with the SEC on February 25, 2019). †
10.20	Loan and Security Agreement dated as of February 1, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders (incorporated by reference herein from our Form 10-Q as filed with the SEC on April 30, 2019). †
10.21	First Amendment to Loan and Security Agreement dated as of October 29, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders. † ü
10.22	Second Amendment to Loan and Security Agreement dated as of December 16, 2019 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders. † ü
10.23	Third Amendment to Loan and Security Agreement dated as of February 27, 2020 by and among GenMark Diagnostics, Inc., and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders. † ü
10.24	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).
10.25	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). *
10.26	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). *
10.27	The GenMark Diagnostics, Inc. 2019 Bonus Plan (incorporated by reference herein from our Form 8-K as filed with the SEC on February 18, 2019). *
10.28	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). *
10.29	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). *
10.30	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010). *

Exhibit	Description
10.31	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). *
10.32	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). *
10.33	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). *
10.34	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). *
10.35	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). *
10.36	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). *
10.37	Employment Offer Letter effective October 12, 2016 by and between GenMark Diagnostics, Inc. and Brian Mitchell. ü*
10.38	The Separation Agreement and General Release made between James McNally and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. ü*
10.39	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). *
10.40	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). *
10.41	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).
10.42	Equity Distribution Agreement dated August 5, 2019, by and among, GenMark Diagnostics, Inc. and Canaccord Genuity LLC (incorporated by reference to our Current Report on Form 8-K filed with the SEC on August 5, 2019).
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

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

ü Included in this filing.

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

Item 16. FORM 10-K SUMMARY

None.

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 March 2, 2020.

GENMARK DIAGNOSTICS, INC.

By: /s/ SCOTT MENDEL
Name: **Scott Mendel**
Title: **Interim President and Chief Executive Officer (principal executive officer)**

March 2, 2020

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

March 2, 2020

POWER OF ATTORNEY

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

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

Signature	Title	Date
/S/ SCOTT MENDEL **Scott Mendel**	Interim President and Chief Executive Officer (principal executive officer)	3/2/2020
/S/ JOHNNY EK **Johnny Ek**	Chief Financial Officer (principal financial and accounting officer)	3/2/2020
/S/ KEVIN O'BOYLE **Kevin O'Boyle**	Chair of the Board	3/2/2020
/S/ DARYL J. FAULKNER **Daryl J. Faulkner**	Director	3/2/2020
/S/ JAMES FOX **James Fox**	Director	3/2/2020
/S/ MICHAEL S. KAGNOFF **Michael S. Kagnoff**	Director	3/2/2020
/s/ LISA M. GILES **Lisa M. Giles**	Director	3/2/2020

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

GenMark Diagnostics, Inc. ("GenMark," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock is based upon our Certificate of Incorporation, as amended (the "Certificate of Incorporation") and our Amended and Restated By-laws, as amended (the "By-laws"). The summary is not complete, and is qualified by reference to our Certificate of Incorporation and our By-laws, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our By-laws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 100,000,000 (One Hundred Million) shares of common stock, $0.0001 par value, and 5,000,000 (Five Million) shares of preferred stock, $0.0001 par value. Our Board of Directors is authorized to establish one or more series of preferred stock and to set the powers, preferences and rights, as well as the qualifications, limitations or restrictions, of such series. These rights of the series of preferred stock may include, without limitation, dividend rights, dividend rates, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions) and liquidation preferences.

Listing

Our common stock is listed and principally traded on The Nasdaq Stock Market LLC (Nasdaq Global Market segment) under the symbol "GNMK."

Voting Rights

The holders of common stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. Except as otherwise provided by law, our Certificate of Incorporation or our By-laws, matters will generally be decided by a majority of the shares present in person or represented by proxy at the meeting and entitled to vote on the matter. Our stockholders do not have the right to vote cumulatively.

Board of Directors

Our By-laws provide that the authorized number of directors shall be fixed from time to time by a resolution duly adopted by the Board of Directors. Our Certificate of Incorporation and By-laws provide that our Board of Directors be classified into three classes, each class to serve for a term of three years and to be as nearly equal in number as possible.

Our By-laws provide that directors may be removed only with cause by the affirmative vote of the holders of a majority of the shares entitled to vote at an election of directors.

Our By-laws provide that a vacancy on the Board of Directors resulting from an increase in the number of authorized directors or death, resignation, retirement, disqualification, removal or other causes shall be filled by a majority of the directors then in office.

Dividend Rights

Subject to any preferential dividend rights granted to the holders of any shares of our preferred stock that may at the time be outstanding, holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board of Directors out of funds legally available therefor.

Rights upon Liquidation

Subject to any preferential rights of outstanding shares of preferred stock, upon any liquidation or dissolution of GenMark, holders of our common stock are entitled to share pro rata in all remaining assets legally available for distribution to stockholders.

Other Rights and Preferences

Our common stock has no sinking fund, redemption provisions, or preemptive, conversion, or exchange rights. There are no restrictions on transfer of our common stock, except as required by law.

Certain Anti-Takeover Effects

Certain provisions of our Certificate of Incorporation and By-laws may be deemed to have an anti-takeover effect.

Business Combinations. Section 203 of the DGCL restricts a wide range of transactions ("business combinations") between a corporation and an interested stockholder. An "interested stockholder" is, generally, any person who beneficially owns, directly or indirectly, 15% or more of the corporation's outstanding voting stock. Business combinations are broadly defined to include (i) mergers or consolidations with, (ii) sales or other dispositions of more than 10% of the corporation's assets to, (iii) certain transactions resulting in the issuance or transfer of any stock of the corporation or any subsidiary to, (iv) certain transactions resulting in an increase in the proportionate share of stock of the corporation or any subsidiary owned by, or (v) receipt of the benefit (other than proportionately as a stockholder) of any loans, advances or other financial benefits by, an interested stockholder. Section 203 provides that an interested stockholder may not engage in a business combination with the corporation for a period of three years from the time of becoming an interested stockholder unless (a) the Board of Directors approved either the business combination or the transaction which resulted in the person becoming an interested stockholder prior to the time that person became an interested stockholder; (b) upon consummation of the transaction which resulted in the person becoming an interested stockholder, that person owned at least 85% of the corporation's voting stock (excluding, for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) shares owned by persons who are directors and also officers and shares owned by certain employee stock plans); or (c) the business combination is approved by the Board of Directors and authorized by the affirmative vote of at least $66^{2/3}$% of the outstanding voting stock not owned by the interested stockholder. The restrictions on business combinations with interested stockholders contained in Section 203 of the DGCL do not apply to a corporation whose certificate of incorporation or bylaws contains a provision expressly electing not to be governed by the statute. Neither our Certificate of Incorporation nor our By-laws contains a provision electing to "opt-out" of Section 203.

Advance Notice and Proxy Access Provisions. Our By-laws require timely advance notice for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders and specify certain requirements regarding the form and content of a stockholder's notice. The chair of the annual meeting has the ability to determine and declare at the meeting that business was not properly brought before the meeting in accordance with the provisions of our By-laws, and, if he or she should so determine, he or she shall so declare at the meeting that any such business not properly brought before the meeting shall not be transacted.

These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed.

Board Classification. Our Certificate of Incorporation and By-laws provide that our Board of Directors is divided into three classes, one class of which is elected each year by our stockholders. The directors in each class serve for a three-year term. Our classified Board of Directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Special Meetings. Special meetings of stockholders may be called at any time by the Chair of the Board, the Board of Directors, or the Chief Executive Officer.

Stockholder Action by Written Consent without a Meeting. Our Certificate of Incorporation provides that any action required or permitted to be taken by the stockholders may be taken without a meeting, without prior notice and without a vote, if a consent in writing, setting forth the action so taken, shall be signed by the holders of record of all of the issued and outstanding capital stock authorized by law or by this Certificate of Incorporation to vote on such action.

Supermajority Approvals. Our Certificate of Incorporation and By-laws provide that certain amendments to our Certificate of Incorporation or By-laws by stockholders will require the approval of two-thirds of the combined vote of our then-outstanding shares of common stock.

Additional Authorized Shares of Capital Stock. The additional shares of authorized common stock and preferred stock available for issuance under our Certificate of Incorporation could be issued at such times, under such circumstances and with such terms and conditions as to impede a change in control.

Choice of Forum.

Our By-laws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our By-laws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Transfer Agent and Registrar

American Stock Transfer & Trust Company, LLC is the transfer agent and registrar for our common stock.

Exhibit 10.21

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of October 29, 2019 (the "**Amendment Effective Date**"), is made among GenMark Diagnostics, Inc., a Delaware corporation ("**GenMark**"), Clinical Micro Sensors, Inc., a Delaware corporation ("**CMS**"), and Osmetech Inc., a Delaware corporation ("**Osmetech**", and together with GenMark and CMS, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of February 1, 2019 (as amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) Effective as of the Amendment Effective Date, the Loan and Security Agreement shall be amended by amending and restating the definition of "**Second Draw Period**" as follows:

"**Second Draw Period**" is the period (i) commencing on the date Borrower provides evidence to Collateral Agent satisfactory to Collateral Agent in its reasonable discretion that Borrower has achieved product revenues (as determined under GAAP) of greater than or equal to $*[***]* for the period of June 1, 2019 through November 30, 2019 and (ii) ending on December 20, 2019.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 5(d), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by Collateral Agent, the Lenders and Borrower.

Certain identified information has been omitted from this document because it is both not material and would be competitively harmful if publicly disclosed, and has been marked with "[***]" to indicate where omissions have been made.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof, *provided*, *further*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date; (b) that there has not been and there does not exist a Material Adverse Change; (c) that, other than as updated by Exhibit A attached hereto, the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date remains true and correct; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 4, each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 4.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Collateral Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document

or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable, documented out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable, documented fees and disbursements of counsel to Collateral Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES that would result in the application of any laws other than the laws OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

GENMARK DIAGNOSTICS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

CLINICAL MICRO SENSORS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

OSMETECH INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

COLLATERAL AGENT AND LENDERS:

SOLAR CAPITAL LTD.,
as Collateral Agent and a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SUNS SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

Exhibit A

Updates to Perfection Certificate

[Intentionally Omitted]

Exhibit 10.22

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of December 16, 2019 (the "**Amendment Effective Date**"), is made among GenMark Diagnostics, Inc., a Delaware corporation ("**GenMark**"), Clinical Micro Sensors, Inc., a Delaware corporation ("**CMS**"), and Osmetech Inc., a Delaware corporation ("**Osmetech**", and together with GenMark and CMS, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of February 1, 2019 (as amended by that certain First Amendment to Loan and Security Agreement dated as of October 29, 2019 (the "**First Amendment**"), and as further amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement.

(a) Effective as of the Amendment Effective Date, the Loan and Security Agreement shall be amended as follows:

(i) Section 2.2(a)(ii). Section 2.2(a)(ii) is hereby amended by replacing "Fifteen Million Dollars ($15,000,000)" with "Twenty Million Dollars ($20,000,000)".

(ii) Lenders and Commitments. Schedule 1.1 of the Loan and Security Agreement, the Schedule of Lenders and Commitments, is hereby amended and restated in its entirety with Annex A hereto.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. Borrower shall have paid (i) to Collateral Agent a fully-earned, non-refundable amendment closing fee in the amount of $*[***]*, to be shared between the Lenders in accordance with their respective Pro Rata Shares, (ii) all invoiced costs and expenses then due in accordance with Section 5(d), and (iii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by Collateral Agent, the Lenders and Borrower.

Certain identified information has been omitted from this document because it is both not material and would be competitively harmful if publicly disclosed, and has been marked with "[***]" to indicate where omissions have been made.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

(d) **Delivery of Documents**. Collateral Agent shall have received on or before the Amendment Effective Date the following, each in form and substance reasonably satisfactory to the Collateral Agent:

(i) An executed Loan Payment Request Form in the form of Exhibit C attached to the Loan and Security Agreement;

(ii) A certificate of a Responsible Officer certifying (x) that Borrower has achieved product revenues (as determined under GAAP) of greater than or equal to $*[***]* for the period of June 1, 2019 through November 30, 2019 and (y) as to the matters set forth in Section 3(c); and

(iii) Such other agreements, instruments, approvals, and other documents, each in form and substance reasonably satisfactory to the Collateral Agent and as the Collateral Agent may reasonably request.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof, *provided*, *further*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date; (b) that there has not been and there does not exist a Material Adverse Change; (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date, as updated by Exhibit A attached to the First Amendment, remains true and correct; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 4, each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 4.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations

under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan and Security Agreement and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Collateral Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable, documented out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable, documented fees and disbursements of counsel to Collateral Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES that would result in the application of any laws other than the laws OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

GENMARK DIAGNOSTICS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

CLINICAL MICRO SENSORS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

OSMETECH INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

COLLATERAL AGENT AND LENDERS:

SOLAR CAPITAL LTD.,
as Collateral Agent and a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SUNS SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

Annex A

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
TOTAL	**$50,000,000.00**	**100.00%**

Term B Loans

Lender	Term Loan Commitment	Commitment Percentage
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
TOTAL	**$20,000,000.00**	**100.00%**

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
[***]	*[***]*	*[***]*
TOTAL	**$70,000,000.00**	**100.00%**

Exhibit 10.23

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of February 27, 2020 (the "**Amendment Effective Date**"), is made among GenMark Diagnostics, Inc., a Delaware corporation ("**GenMark**"), Clinical Micro Sensors, Inc., a Delaware corporation ("**CMS**"), and Osmetech Inc., a Delaware corporation ("**Osmetech**", and together with GenMark and CMS, individually and collectively, jointly and severally, "**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of February 1, 2019 (as amended by that certain First Amendment to Loan and Security Agreement dated as of October 29, 2019 (the "**First Amendment**"), as further amended by that certain Second Amendment to Loan and Security Agreement dated as of December 16, 2019, and as further amended, restated or modified from time to time, the "**Loan and Security Agreement**"). Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 **Definitions; Interpretation.**

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 **Amendments to the Loan and Security Agreement.**

(a) Effective as of the Amendment Effective Date, the Loan and Security Agreement shall be amended by amending and restating the following definitions as follows:

(i) "**Amortization Date**" is, March 1, 2021; provided that if the Interest Only Extension Conditions are satisfied and the Borrower so elects in writing, then March 1, 2022.

(ii) "**Interest Only Extension Conditions**" are satisfaction of each of the following: (a) no Default or Event of Default shall have occurred and is continuing and (b) Borrower shall have provided evidence to Collateral Agent satisfactory to Collateral Agent in its reasonable discretion that Borrower has achieved product revenues (as determined under GAAP) of greater than or equal to $*[***]* on a trailing six-month basis for the period ending March 31, 2020.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 **Conditions of Effectiveness.** The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

Certain identified information has been omitted from this document because it is both not material and would be competitively harmful if publicly disclosed, and has been marked with "[***]" to indicate where omissions have been made.

(a) **Fees and Expenses**. Borrower shall have paid (i) to Collateral Agent a fully-earned, non-refundable amendment closing fee in the amount of $*[***]*, to be shared between the Lenders in accordance with their respective Pro Rata Shares, (ii) all invoiced costs and expenses then due in accordance with Section 5(d), and (iii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by Collateral Agent, the Lenders and Borrower.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

(iii)

SECTION 4 **Representations and Warranties**. To induce the Lenders to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided, however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof, *provided, further*, that to the extent such representations and warranties by their terms expressly relate only to a prior date such representations and warranties shall be true and correct as of such prior date; (b) that there has not been and there does not exist a Material Adverse Change; (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date, as updated by Exhibit A attached to the First Amendment, and as further updated by Exhibit A attached hereto, is true and correct; (d) Lender has and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lender, pursuant to the Loan Documents or otherwise granted to or held by Lender; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 4, each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 5 **Miscellaneous.**

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms its Obligations under the Loan and Security Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 4.1 of the Loan and Security Agreement, (3) reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, and with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan and Security Agreement and (5) agrees that the Loan and Security Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Collateral Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **No Reliance**. Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable, documented out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable, documented fees and disbursements of counsel to Collateral Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law**. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES that would result in the application of any laws other than the laws OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

GENMARK DIAGNOSTICS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

CLINICAL MICRO SENSORS, INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

OSMETECH INC.,
as Borrower

By: /s/ Johnny Ek
Name: Johnny Ek
Title: CFO

COLLATERAL AGENT AND LENDERS:

SOLAR CAPITAL LTD.,
as Collateral Agent and a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SUNS SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

SCP PRIVATE CREDIT INCOME FUND SPV LLC,
as a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

Exhibit A

[Intentionally Omitted]

Exhibit 10.37

5964 La Place Court
Carlsbad, CA 92008
www.genmarkdx.com

October 12, 2016

Brian Mitchell
[ADDRESS]

Dear Brian:

Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics ("GenMark Dx") is pleased to offer you employment in the position of VP, Operations, reporting to Hany Massarany, with a start date of Monday, November 7, 2016.

Your annual gross salary will be $240,000 to be paid on a bi-weekly basis in keeping with GenMark Dx's standard payroll practices and procedures. In addition, you will be eligible to participate in the GenMark Dx performance incentive bonus program with a potential variable earning opportunity of 40% of your base salary beginning with the performance period of January 1, 2017 to December 31, 2017.

We are also pleased to inform you that the Company will recommend for you to be granted 30,0000 GenMark Diagnostics, Inc. Restricted Shares subject to board approval and blackout windows. The shares will be granted at the closing price on the date of the grant. The Restricted Shares vesting schedule would be a 25% cliff vest at the one year anniversary of the date of grant and the remaining 75% in equal quarterly installments for three years thereafter.

Additionally, as a member of the GenMark Dx Senior Leadership Team, you will also be eligible for accelerated vesting upon a Change in Control, per GenMark Dx's "Amendment of Stock Option Agreement."

The Company will also provide you with a signing bonus of $25,000 payable as soon as practicable following your start date. In the event that you terminate voluntarily from the company within one (1) year of employment, GenMark may seek a pro-rated reimbursement of your signing bonus.

You will also be entitled to participate in the benefit plans offered by GenMark Dx, subject to the eligibility requirements, terms and conditions of those plans. The benefits offered at this time include 15 vacation days, 10 sick days, holiday pay, life insurance, health insurance, disability insurance, Employee Stock Purchase Plan, and a 401k plan, in accordance with GenMark Dx policies and subject to the company's right to modify, add, and delete any benefit plan.

You understand and agree that during your employment you are required to comply with GenMark Dx's policies and procedures. In making you this offer, we relied on your representation that you are not bound by any non-compete or non-solicitation provision that would prevent or restrict you from carrying out your job responsibilities for GenMark Dx. You also promise and represent that you will not bring with you to GenMark Dx, or use while employed by the Company, any confidential or trade secret information of a previous employer.

In addition, as a condition of accepting this offer, you are also agreeing that you have reviewed and signed the enclosed Confidentiality and Invention Assignment Agreement.

Employment with GenMark Dx is "employment at will." This means that your employment is not for a designated period of time and that either you or GenMark Dx can terminate the employment at any time, with or without cause. The at-will nature of this employment relationship cannot be changed except by an express written agreement signed by the Chairman of GenMark Dx. The other terms of this offer of employment may not be amended without an express written agreement signed by both parties.

This job offer is also contingent upon successful completion of a post offer, pre-employment background check and drug screen.

Please sign the acceptance below and sign the enclosed Confidentiality and Invention Assignment Agreement to formally accept this offer of employment. This offer will expire by Friday, October 14, 2016 if not accepted beforehand.

Congratulations and we look forward to welcoming you to the GenMark Dx team during this very exciting phase of our company's transition.

Sincerely,

/s/ Jennifer Williams

Jennifer Williams
SVP, Human Resources

By accepting, I agree to all terms of this offer and the Confidentiality and Invention Assignment Agreement.

/s/ Brian Mitchell

October 13, 2016

Exhibit 10.38

SEPARATION AGREEMENT AND GENERAL RELEASE

This Separation Agreement and General Release (this "Agreement") is made between **James McNally** on behalf of him/herself, his/her agents, assignees, heirs, executors, administrators, beneficiaries, trustees and legal representatives ("Employee"), and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (together with GenMark Diagnostics, Inc., the "Company"). Employee and the Company are each a "Party" and are together sometimes referred to as "Parties" to this Agreement. Capitalized terms used but not defined herein shall have the meaning given to such terms in the GenMark Diagnostics, Inc. Executive Severance Plan (the "Severance Plan").

In consideration of the promises in this Agreement, the adequacy of which is hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. Separation Date: Employee's employment with the Company will cease effective **January 10, 2020** (the "Separation Date").

2. Consideration. In consideration of Employee executing this Agreement and complying with its terms, the Company agrees to:
   a. pay Employee an aggregate gross lump sum payment of ONE HUNDRED FORTY-FIVE THOUSAND ONE HUNDRED ONE AND 32/100 DOLLARS (**$145,101.32**), representing six (6) months of Employee's Base Salary Rate payable pursuant to Section 6.1(a) of the Severance Plan within ten (10) business days after the date both Parties have signed this Agreement;

   b. pay Employee an amount equal to: (x) Employee's target bonus percentage under the 2019 Bonus Plan (i.e., 50% of Employee's base salary as of the Separation Date), multiplied by (y) the percentage achievement of the Company-level performance targets under the Company's 2019 Bonus Plan as approved by the Company's Board of Directors (and without modification upward or downward based on individual performance), payable upon the later of (i) ten (10) business days after the date both Parties have signed this Agreement, or (ii) the date the Company pays bonus awards to Company employees in accordance with the 2019 Bonus Plan; and

   c. provide that the restricted stock units set forth on Exhibit A hereto (the "Severance Equity") granted under the terms of the Company's 2010 Equity Incentive Plan (as amended, the "2010 Plan") shall continue to remain outstanding and vest, and be issued to Employee, within ten (10) business days after the date both Parties have signed this Agreement.

3. Health Care Coverage. If Employee elects to continue and remains eligible for COBRA benefits pursuant to Section 6.1(b) of the Severance Plan, the Company will pay for and provide the health care benefits as set forth therein.

4. Outplacement Services. The Company will provide Employee with an outplacement services package selected by the Company following the receipt of this Agreement signed in full and on the condition that Employee performs his/her obligations hereunder. In no event will Employee receive cash or other benefits in lieu of outplacement services.

5. Transition Services. Promptly following the Separation Date, Employee agrees to reasonably cooperate with the Company to transition Employee's existing work to other Company employees.

6. Treatment of ESPP Contributions and Other Equity Awards. Any contributions made by Employee into the Company's Amended and Restated 2013 Employee Stock Purchase Plan (the "ESPP") in respect of any ESPP plan period that does not conclude prior to the Separation Date will be refunded to Employee in accordance with the terms of the ESPP. In addition, any restricted stock units, stock options or other equity Awards held by the Employee which remain unvested as of the Separation Date (other than the Severance Equity) will be cancelled and terminated in their entirety without further action of the Parties pursuant to the terms of the 2010 Plan.

7. No Consideration Absent Execution of this Agreement. Employee understands and agrees that Employee would not receive the consideration and/or benefits specified in Sections 2, 3 and 4 above (collectively, the "Separation Benefits"), except for Employee's execution of this Agreement and the fulfillment of the covenants contained herein.

8. Consideration Sufficiency. Employee acknowledges and agrees that the Separation Benefits are contingent upon the Company receiving an executed copy of this Agreement no later than **January 16, 2020**, and that Employee performs all of his/her obligations hereunder. Employee acknowledges that the Separation Benefits are greater than that which Employee would otherwise be entitled to in the absence of this Agreement.

9. Payment of Wages. On the Separation Date, the Company will pay Employee all Accrued Amounts earned through the Separation Date, subject to all required payroll deductions and withholdings.

10. Tax Matters. The Company will withhold required federal, state and local taxes from any and all payments contemplated by this Agreement. Other than Company's obligation and right to withhold, Employee will be responsible for any and all taxes, interest, and penalties that may be imposed with respect to the payments contemplated by this Agreement (including, but not limited to, those imposed under Internal Revenue Code Section 409A).

11. Release of Claims. In consideration of the Company's execution of this Agreement and other good and valuable consideration, Employee hereby forever and irrevocably releases and discharges the Company, and any parent (including GenMark Diagnostics, Inc.), subsidiary, affiliated, and related entities, including their past, present, or future managers, directors, administrators, officers, employees, agents, insurance companies, attorneys, representatives, predecessors, successors and assigns, and each of them (collectively, the "Released Parties") from all known and unknown claims, liabilities, and obligations of every kind (including attorneys' fees and costs) that Employee has ever had or now may have against the Released Parties arising out of or relating to facts, events, occurrences, or omissions up to and including the date this Agreement is fully executed by the Parties. The claims that Employee is releasing include: (a) claims arising out of Employee's employment with the Company and his/her separation from such employment; (b) claims for breach of express or implied contract or covenant of good faith and fair dealing; (c) all claims for harassment, discrimination or violation of public policy; (d) claims for constructive discharge or wrongful discharge; (e) claims for retaliation; (f) claims for violation of state or federal common law or statutory law, including to the extent applicable, all claims arising under the California Constitution, the California Fair Employment and Housing Act, the California Labor Code, including sections 970 *et. seq.*, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the California Unruh Act, the Worker Adjustment and Retraining Notification Act (WARN), California WARN, the Equal Pay Act, California Business & Professions Code, including sections 17200 *et seq*., the Fair Labor Standards Act, the Employee Retirement Income Security Act, the National Labor Relations Act, the California Family Rights Act, the Family and Medical Leave Act, the Americans with Disabilities Act, the Genetic Information Nondiscrimination Act, the Private Attorneys General Act of 2004, and the Sarbanes-Oxley Act of 2002, or other federal, state, or local laws relating to employment or separation from employment or benefits associated with employment or separation from employment; (g) claims for emotional distress, mental anguish, humiliation, and personal injury; and (h) claims that may be asserted on Employee's behalf by others. Excluded from this Release are claims which cannot be waived or released as a matter of law.

YOU UNDERSTAND AND ACKNOWLEDGE THAT YOU HAVE BEEN ADVISED TO SEEK THE ADVICE OF AN ATTORNEY, IF YOU SO CHOOSE, PRIOR TO SIGNING THIS RELEASE AND TO THE EXTENT DESCRIBED HEREIN YOU ARE GIVING UP ANY LEGAL CLAIMS YOU HAVE AGAINST THE COMPANY AND EACH OF ITS RESPECTIVE CURRENT, FORMER OR FUTURE OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, REPRESENTATIVES, SHAREHOLDERS, LEGAL PREDECESSORS AND SUCCESSORS, BY SIGNING THIS RELEASE.

12. No Further Obligations of Company. Employee acknowledges that the Separation Benefits and other considerations provided to him/her are in full and complete satisfaction and discharge of any and all obligations that the Company or any of the Released Parties has or may have to Employee.

13. Representation of No Action; Agreement Not to Sue. As a condition of receiving the Separation Benefits and other consideration provided, Employee agrees not to sue in civil court any of the Released Parties regarding any claim that has been released in this Agreement. Employee represents and agrees that he/she has not initiated any claim, charge, lawsuit, or other action against any of the Released Parties and that he/she has not transferred or assigned that right to any other person or entity. Should any third party, including any state or federal agency, bring any action or claim against the Company or any of the Released Parties on Employee's behalf, Employee acknowledges and agrees that this Agreement provides full relief and Employee will not accept any other relief. The prohibitions on further recovery in this Section 13 will not apply to any recovery authorized under Section 21F of the Securities Exchange Act of 1934.

14. Waiver of Civil Code Section 1542. Employee acknowledges that he/she has been made aware of and expressly waives any and all rights under Section 1542 of the California Civil Code to the full extent that such rights may be waived. Section 1542 provides as follows:

"A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."

15. Non-Disparagement. Employee agrees not to make or cause to be made any statements that disparage, are inimical to, or damage the reputation of the Company or any of its past or present affiliates, subsidiaries, agents, officers, directors or employees to anyone, including, but not limited to, current Company employees, the media, regulatory agencies, public interest groups, and publishing companies.

16. Return of Company Property. Employee agrees to promptly return to the Company all hard copy and electronic documents (and all copies thereof) and other Company property that Employee has had in Employee's possession at any time, including, but not limited to, files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information (including email), tangible property (laptop computer, cell phone, PDA, etc.), credit cards, entry cards, identification badges and keys, and any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). If Employee discovers after the Separation Date that Employee has retained any Company proprietary or confidential information, Employee agrees, immediately upon discovery to contact the Company and make arrangements for returning the information.

17. Post-Employment Obligations. Employee acknowledges his/her continuing obligations under Employee's Confidentiality and Non-Disclosure Agreement (the "NDA") which prohibits disclosure of any confidential or proprietary information of the Company. A copy of the NDA is attached. Pursuant to the federal Defend Trade Secrets Act of 2016, Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Moreover, if Employee files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Employee may disclose a trade secret to Employee's attorney and use the trade secret information in the court proceeding; provided, however that Employee: (i) shall file any document containing the trade secret under seal; and (ii) shall not disclose the trade secret, except pursuant to a court order.

18. Breach of Agreement. If Employee breaches any of Employee's obligations under this Agreement (including, but not limited to, Employee's obligations relating to Confidentiality, Return of Company Property, and Post-Employment Obligations), Company's obligations under this Agreement will immediately be terminated, no further performance under this Agreement will be required by the Company, and Employee shall immediately return to the Company any payments and other consideration previously paid or provided to Employee by the Company under this Agreement.

19. No Admission. Employee understands that the Released Parties expressly deny any wrongdoing or liability to Employee.

20. Severability. If any portion of this Agreement is void or deemed unenforceable for any reason, the unenforceable portion will be deemed severed from the remaining portions of this Agreement, which will otherwise remain in full force.

21. Review and Return of Agreement. Employee has seven (7) days from the date of this Agreement to review and execute this Agreement (although Employee may choose to voluntarily execute this Agreement earlier). This Agreement will not be effective or enforceable until after the delivery of a signed copy of the Agreement to the Company at 5964 La Place Court, Carlsbad CA, 92008, Attention: Hollis Winkler, Vice President, Human Resources.

22. Material Non-Public Information. Employee hereby acknowledges that as of the date of this Agreement, Employee is a holder of the Company's equity securities. Employee hereby further acknowledges that he/she is aware that United States securities laws prohibit any person who has received from an issuer material non-public information from purchasing or selling securities of such issuer or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities. Employee shall not trade in the securities of the Company on the basis of, or while Employee is in possession of, material non-public information regarding the Company. Nothing contained in this Agreement shall create any presumption that any information supplied to Employee is in fact material and non-public, nor shall anything contained herein shift the burden of proof imposed by applicable law absent this Agreement with respect to establishing whether any such information is material and non-public.

23. Applicable Law. This Agreement will be governed by California law. Venue for all disputes will be in San Diego County, California and each Party agrees not to assert lack of jurisdiction as an objection to any action brought in San Diego, California.

24. Multiple Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Executed faxed copies or PDF copies transmitted via email will be effective and enforceable.

25. Headings. Headings in this Agreement are inserted for reference and convenience only and are not a part of this Agreement.

26. Interpretation, Entire Agreement. This Agreement replaces and supersedes all other agreements, verbal or written, which are merged into this Agreement, and constitutes the entire agreement of the Parties. Any rule of law or decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it has no application and is expressly waived. Further, the Parties agree that the term “including” and its variations are always used in the non-restrictive sense as if followed by “but not limited to.”

27. Modification and Waiver. Any modification of this Agreement will be effective only if it is in a writing signed by the Parties to this Agreement. No waiver of any of the provisions of this Agreement will constitute a waiver of any other provision, even if similar, nor will any waiver constitute a continuing waiver. No waiver will be binding unless executed in writing by the Party making the waiver.

28. Expiration of Offer. The offer made by the Company pursuant to this Agreement shall be null and void if it is not accepted in writing by Employee on or before the expiration of the 7-day period described in Section 8 above.

[Continued on next page]

Employee and the Company, by their signatures below, acknowledge that, other than the NDA which remains in effect, there exist no other promises, representations, or agreements between them and that they voluntarily enter into this Agreement with the intent to be legally bound.

/s/ James McNally DATE: _14-Jan-2020_____
James McNally

/s/ Hollis Winkler DATE: _9-Jan-2020_____
James McNally
Vice President, Human Resources

Exhibit A
Severance Equity

RSU Grant Number	Vest Date	Grant Date	Total Shares
000200	2/1/2020	11/2/2016	2,031
000540	2/22/2020	2/22/2017	625
000825	2/1/2020	10/27/2017	625
001130	2/23/2020	2/23/2018	5,859
001399	1/26/2020	10/26/2018	1,250
001584	2/18/2020	2/18/2019	25,312
Total			**35,702**

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

of our reports dated March 2, 2020, with respect to the consolidated financial statements of GenMark Diagnostics, Inc. and the effectiveness of internal control over financial reporting of GenMark Diagnostics, Inc. included in this Annual Report (Form 10-K) of GenMark Diagnostics, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

San Diego, California
March 2, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott Mendel, certify that:

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

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/2/2020

By: /s/ Scott Mendel

Scott Mendel

Interim President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Johnny Ek, certify that:

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

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

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

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

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/2/2020

By: /s/ Johnny Ek

Johnny Ek

Chief Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of GenMark Diagnostics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Scott Mendel, Interim President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: 3/2/2020

By: /s/ Scott Mendel
Scott Mendel
Interim President and Chief Executive Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of GenMark Diagnostics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Annual Report of GenMark Diagnostics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Johnny Ek, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(i) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: 3/2/2020

By: /s/ Johnny Ek
Johnny Ek
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of GenMark Diagnostics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.