GENMARK DIAGNOSTICS, INC.

FORM 10-K
(Annual Report)

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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, 2016

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

For the transition period from to
Commission File Number: 001-34753

GenMark Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**27-2053069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5964 La Place Court, Carlsbad, California	**92008-8829**
(Address of principal executive offices)	**(Zip code)**

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

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

Title of Each Class:	**Name of Each Exchange on which Registered:**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC (NASDAQ Global Market)**

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

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

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 ☒

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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

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

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

As of June 30, 2016, 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 $350,814,000 based on the closing sale price for the registrant's common stock on the NASDAQ Global Market on that date of $8.70 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 24, 2017 was 47,051,202 . 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, 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 ® and ePlex ® and our other logos and trademarks are the property of GenMark Diagnostics, Inc. or its subsidiaries. All other brand names or trademarks appearing in this Annual Report are the property of their respective holders. Our use or display of other parties' trademarks, trade dress or products in this Annual Report does not imply that we have a relationship with, or the endorsement or sponsorship of, the trademark or trade dress owners.

Use of External Estimates

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

PART I.

Item 1. BUSINESS

GenMark Diagnostics, Inc., or GenMark, is a molecular diagnostics company focused on developing and commercializing multiplex molecular tests that aid in the diagnosis of complex medical conditions and help guide therapy decisions. 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, simple to perform, clinically relevant multiplex molecular tests based on our proprietary eSensor electrochemical detection technology. We currently sell our XT-8 instrument and related diagnostic and research tests, as well as certain custom manufactured reagents, which collectively we refer to as our XT-8 system. Our XT-8 system supports a broad range of molecular tests with a compact and easy-to-use workstation and disposable test cartridges. In addition, we have developed and are commercializing of our sample-to-answer ePlex instrument and Respiratory Pathogen (RP) Panel. We intend to offer a number of additional associated diagnostic tests for use with our ePlex instrument, which we collectively refer to as our ePlex system.

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 year ended December 31, 2016 and 2015 were approximately $50.6 million and $42.2 million , respectively. As of December 31, 2016 , we had an accumulated deficit of $355.3 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 commercialize our ePlex system, as well as to further increase our manufacturing capabilities and domestic and international 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:

- ***Successfully Commercialize our ePlex System*** . We believe the ePlex system is an attractive solution for a broad range of hospitals and laboratories that 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 system that we believe will satisfy important medical needs and present attractive commercial opportunities. For example, in June 2016 we obtained CE Mark of our ePlex instrument and RP Panel, and in December 2016 we submitted 510(k) applications to the United States Food and Drug Administration, or the FDA, for our ePlex instrument and RP Panel. During 2017, we intend to complete the development of, CE Mark, and submit 510(k) applications to the FDA our ePlex blood culture identification (BCID) family of panels, which include a gram-positive (GP), a gram-negative (GN), and a fungal pathogen panel. In addition, we are actively evaluating the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.
- ***Grow our Installed Base of Customers*** . We have identified those laboratories and hospitals that we believe will benefit from our product portfolio. We intend to leverage our commercial organization to drive placements of our ePlex system both domestically and internationally. We anticipate that the expansion of our installed base of customers will drive sales of our test cartridges, from which we anticipate generating 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 reimbursement support. These activities are designed to aid in establishing the clinical and health economic utility of multiplex molecular diagnostic tests, which we believe will increase adoption of our products.

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

Our Technology

Our eSensor Technology

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

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

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

Our XT-8 and ePlex test 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 a polymerase chain reaction, or 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 XT-8 System . 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 cartridges are placed. The test cartridge modules operate independently of each other allowing up to 24 independent test cartridges to be loaded at one time, with the remaining modules available for use at any future time while the system is running.

We believe that our XT-8 system offers reference laboratories and hospitals the following benefits:

Key Features & Benefits	Description
Broad Test Menu	We offer the following four FDA-cleared assays on our XT-8 instrument: a Respiratory Viral Panel, Cystic Fibrosis Genotyping Test, Thrombofilia 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 research use only (RUO).
Fast Turnaround	Approximately 30 minutes post-PCR to result from an amplified DNA sample with minimal technician time needed.
Accurate Results	Our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards.
Ease of Use	Minimal manual processing steps, intuitive touch-screen interface and clear result reports.
Random Access	Each of up to 24 test cartridge modules can be accessed independently resulting in a highly flexible workflow.
Minimal Maintenance	No routine maintenance or calibration is required.
Multiplex Capability	Detects numerous distinct biomarkers in a single sample reducing the need for reflex testing.

Our ePlex System. 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 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 believe our ePlex system offers reference laboratories and hospitals the following benefits:

Key Features & Benefits	Description
Broad Test Menu	We obtained CE Mark for our ePlex system and RP Panel in June 2016, and filed 510(k) applications with the FDA for the ePlex instrument and RP Panel in December 2016. During 2017, we intend to complete the development of, CE Mark, and submit 510(k) applications to the FDA our ePlex blood culture identification (BCID) family of panels, which include a gram-positive (GP), a gram-negative (GN), and a fungal pathogen panel. In addition, we are actively evaluating the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.
Ease of Use	Minimal manual processing steps, intuitive touch-screen interface and clear result reports.
True Sample-to-Answer	The user simply adds a raw or minimally prepared sample to the test cartridge and inserts the cartridge into the instrument.
Fast Turnaround	Results are capable of being produced in approximately 1-2 hours from sample input.
Random Access	Each of up to 24 test cartridge modules can be accessed independently resulting in a highly flexible workflow.
Minimal Routine Maintenance	Minimal maintenance or calibration is required.
Multiplex Capability	Detects numerous distinct biomarkers in a single sample reducing the need for reflex testing.
Positive Patient Identification (PosID)	Incorporates patented positive patient identification technology to reduce sample reporting errors.
IT Integration	Multiple design features to improve operational efficiency, such as bi-directional laboratory information system (LIS) connectivity and remote access capability to reduce downtime and service costs.

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 are active participants 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 tests. 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 tests to historical or "gold standard" tests, and demonstrating that our tests 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 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 currently outsource the manufacture of our XT-8 instrument to Leica Biosystems Melbourne Pty Ltd., or Leica, and outsource the manufacture of our ePlex instrument to Plexus Corp, or Plexus. 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 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 and Europe, 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 utilize a direct sales and technical support team to sell our ePlex system in certain key European countries, which are augmented by distributors in other locations internationally.

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

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

- ***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.
- ***Reagent Rental:*** A reagent rental agreement requires that a customer commit 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.

Customers

Our target customers include hospital-based laboratories and research institutions. We believe our ePlex system will expand our current potential user base from approximately 1,000 domestic customers to approximately 12,000 potential customers globally. In 2016 and 2015, Laboratory Corporation of America, Inc. represented 27% and 17%, respectively, of our total revenue. In 2014, no single customer represented more than 10% 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 Cephied), Siemens, Hologic, Inc., Seegene, Roche Diagnostics and Abbott Molecular Diagnostics. Our diagnostic tests also face competition with laboratory developed tests, or 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 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 30 pending applications, provides 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. A majority of our issued and exclusively licensed patents are scheduled to expire by 2021, with approximately one half of the patents expiring by 2018. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2034. 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 eSensor®, word and design marks for GenMark®, GenMark DX®, eSensor®, XT-8®, eSensor XT-8®, ePlex®, and GenMark 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 kits and instrumentation systems. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution.

The two primary types of FDA marketing authorization required applicable to a device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA. We have obtained 510(k) 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. In December 2016, we filed 510(k) applications with the FDA for our ePlex instrument and RP Panel.

Proposed Regulation of Laboratory Developed Tests (LDTs). In October 2014, the FDA promulgated draft guidance which describes a new proposed regulatory framework for LDTs. Based on this proposal, clinical laboratories that develop and use LDTs would be required to comply with specific regulatory requirements (e.g., adverse even reporting, quality system regulation, or QSR, premarket submission, and FDA review) prior to the use of LDTs for clinical diagnostic purposes. The timeline for phasing in the proposed regulatory requirements would begin upon finalization of the FDA guidance document. The ultimate impact of this draft guidance on our customers remains uncertain.

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, or GMP, requirements, 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 FDA's GMP requirements.

Because we are a medical device manufacturer, we must also comply with 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, or 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." We expect that most of our products will be categorized as "high complexity," since most molecular diagnostic tests are currently FDA-cleared as CLIA "high complexity" devices.

Foreign Government Regulation . We intend to market our products in European and other select 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, or the FCA, that are intended to reduce waste, fraud and abuse in the health care industry. These laws are broad and subject to evolving interpretations. They prohibit many arrangements and practices that are lawful in industries other than health care, including certain payments for consulting and other personal services, some discounting arrangements, the provision of gifts and business courtesies, the furnishing of free supplies and services, and waivers of payments. In addition, many states have enacted or are considering laws that limit arrangements between medical device manufacturers and physicians and other health care providers and require significant public disclosure concerning permitted arrangements. These laws are vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. We must operate our business within the requirements of these laws and, if we were accused of violating them, we could be forced to expend significant resources on investigation, remediation and monetary penalties.

Patient Protection and Affordable Care Act

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. We are unable to predict whether the suspension will be continued beyond 2017. 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, 2016 , we had 308 employees, of which: 163 employees were involved in research and development; 51 in operations, manufacturing and quality assurance; 62 in sales and marketing; and 32 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.

Corporate and Available Information

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

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

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 be unsuccessful in obtaining FDA clearance for our ePlex system within our expected timeframe.

We are investing significantly in the commercialization of our ePlex instrument and the development of its related molecular diagnostic panels to expand our future product offerings. Our ePlex system requires 510(k) clearance or pre-market approval by the FDA prior to marketing it for clinical use in the United States. In December 2016, we filed 510(k) applications with the FDA for our ePlex instrument and RP Panel. There are a number of potential risks associated with conducting clinical trials and obtaining regulatory clearance for our ePlex system. For example, we may have difficulty maintaining the level of product reliability and clinical accuracy required to obtain FDA clearance or approval for our ePlex system. 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 our ePlex system in the United States. We may be unsuccessful in obtaining FDA clearance for our ePlex system within our expected timeframe, or at all, which could adversely impact our future financial performance and cause our stock price to decline.

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.

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 our product development timelines. If we or our key suppliers continue to encounter difficulties in producing sufficient yields of high quality products or product components, or scaling manufacturing operations as a result of, among other things, process and manufacturing transfer complexities, quality control and quality assurance issues, and/or availability of subcomponents, equipment and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results or product development goals within the time frame we expect, or at all. In addition, finding solutions to product quality, reliability, and variability 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, and warranty and service obligations.

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

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, acceptable manufacturing costs and complying with regulatory requirements. Our instrument systems and certain critical components are custom-made by only a few outside suppliers. In certain instances, we and our customers have a sole source supply for certain key products, product components and ancillary items used to run our tests. If we are unable to satisfy our forecasted demand from existing suppliers for our products, or we or our customers are unable to find alternative suppliers for key product components or ancillary items 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 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 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 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 facility 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.

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

In June 2016, we obtained CE Mark under the European In-Vitro Diagnostic Devices Directive (98/79/EC) for our ePlex instrument and ePlex RP Panel. We are commercializing our ePlex system in Europe utilizing a direct sales and technical support team in certain key European countries, which we have augmented with a third party logistics provider that is responsible for managing the international delivery of our products and providing certain other related services. We have also engaged a number of distributors in certain European countries and intend to further expand internationally over time. If we are

unable to establish the infrastructure or recruit highly qualified personnel to support our international direct sales and support organization, if we fail to adequately plan for or integrate our direct sales activities with those of our third party logistics provider, or if we are unsuccessful in developing awareness and acceptance of our products and technology internationally, our anticipated revenue growth internationally may not materialize, 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, any distributors we establish in particular geographic regions may not commit the necessary resources to market and sell our products to meet our expectations. If 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.

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 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 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, 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 tests 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 intensity of competition to increase. We compete with companies engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Categories of our competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, including: Luminex; Nanosphere, Inc. (which was acquired by Luminex in June 2016); bioMerieux (which acquired BioFire Diagnostics, Inc.); Abbott Molecular Diagnostics; Hologic, Inc.; Seegene and Cepheid (which was acquired by Danaher Corporation);
- 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: Cepheid; Siemens; Hologic, Inc.; Qiagen NV; bioMérieux; Roche Diagnostics; and Abbott Molecular Diagnostics.

Our diagnostic tests 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 trials 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, 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.

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

Revenue from our infectious disease products fluctuates based upon the occurrence of related outbreaks and changes in testing recommendations and available therapies. Influenza and other respiratory-related outbreaks are usually more concentrated in the first and fourth quarters of the year. New information or the introduction of advanced treatment options with respect to a particular disease may also affect 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 changes to infectious disease testing recommendations affecting our products. As a result of one or more of these factors, we may not be able to accurately forecast sales from our infectious disease products.

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

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

Our largest customer, Laboratory Corporation of America, Inc., accounted for approximately 27% of our total revenue for the fiscal year ended December 31, 2016. The loss of a significant customer or a significant reduction in the amount of product ordered by our significant customers may adversely affect our revenue, results of operations and cash flows.

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

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

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

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products, as well as our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with our ePlex system. We may be unable to reduce our expenditures in a

timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our business and financial condition.

Our credit facility requires that we satisfy certain milestones in order to access funding and contains restrictions that limit our flexibility in operating our business.

In January 2015, we entered into a Loan and Security Agreement, or the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other lenders. Pursuant to the LSA, as amended, we borrowed $10 million in March 2015 and another $10 million in June 2016. We may borrow up to an additional $15 million if we timely obtain FDA clearance of our ePlex system. In addition, we have access to up to $5 million under a revolving credit facility, subject to certain conditions and a defined borrowing base. If we fail to satisfy the conditions to funding under our credit facility, including, but not limited to, as a result of our failure to timely achieve FDA clearance of our ePlex system, we may not have the ability to borrow additional amounts under our credit facility.

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

Until such time, if ever, as we can generate positive cash flows from operations, we will be required to finance our operations with our cash resources and amounts made available under our credit facility. We may need to raise additional funds in the future to support our operations. We cannot be certain that additional capital will be available as needed, on acceptable terms, or at all. If we require additional capital at a time when investment in our company, in molecular diagnostics companies, or the marketplace in general is limited, we may not be able to raise such funds at the time that we desire, or at all. If we do raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be significantly diluted. In addition, newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds through collaborations and licensing arrangements, we could be required to relinquish significant rights to our technologies and products, or grant licenses on terms that are not favorable to us.

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. Our net losses were approximately $50.6 million and $42.2 million for the years ended December 31, 2016 and 2015 , respectively. As of December 31, 2016 , we had an accumulated deficit of $355.3 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), research and development, manufacturing, clinical and regulatory 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.

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.

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 proposing to update the European Directive 98/79/EC on in vitro diagnostic medical device, or IVD Directive (IVDD), that could impact the classification of our molecular diagnostic products and 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. 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, or RUO, tests and custom manufactured reagents, which are not intended for diagnostic purposes. Clinical laboratories are regulated under CLIA and may validate the clinical diagnostic use of an LDT specifically for use in their laboratory using any labeled products. The FDA has traditionally practiced enforcement discretion regarding the use of the LDTs for clinical diagnostic purposes. However, the FDA has recently promulgated draft guidance which outlines stringent regulatory requirements for CLIA labs in order to use LDTs for clinical diagnostic application. These proposed requirements, if implemented, may result in a significant reduction in the sale of our RUO or custom manufactured products, which could reduce our revenues and adversely affect our operations and/or financial condition.

If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, 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 manufacturing of our instruments and much of the disposable component molding for our test cartridges. Leica, the contract manufacturer of our XT-8 instruments, and Plexus Corp., the contract manufacturer of our ePlex instrument, both specialize in the manufacturing of electronic and electro-mechanical devices. While we work closely with Plexus and Leica to ensure continuity of supply while maintaining high quality and reliability, 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 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 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 Medicine and Medicaid Services, or, CMS, released the final rule implementing the federal Physician Payments Sunshine Act, or the Sunshine Act. The law requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals. These reporting requirements took effect on August 1, 2013. Failure to submit required information may result in significant civil monetary penalties. We expect compliance with the PPACA and Sunshine Act to impose significant administrative and financial burdens on us.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase 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 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. 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 2013 through 2015. recently, Congress and the new administration have proposed and taken various steps to revise, repeal, or delay implementation of various aspects of PPACA. If the PPACA is significantly revised, repealed, or if implementation of various aspects are delayed, such modification, repeal, or delay may impact our business, financial condition, results of operations, cash flows and the trading price of our securities. Complying with PPACA may significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

In August 2011, President Obama signed into law the Budget Control Act of 2011, which among other things, created automatic reductions to several government programs, including aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. In April 2013, the 2% Medicare payment reductions went into effect. In addition to the potential impacts to PPACA under the new administration, there could be sweeping changes to the Budget Control Act and other healthcare reforms. 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.

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

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

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

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

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

Our commercial success is dependent in part on obtaining, maintaining and enforcing intellectual property rights, including our patents and other intellectual property rights. If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products that are substantially the same as ours without incurring the sizeable 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 30 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. A majority of our issued and exclusively licensed patents are scheduled to expire by 2021, with approximately one half of the patents expiring by 2018. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2034. 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 any of our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to

our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

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

Our manufacturing processes and facilities and those of some of our contract manufacturers must comply with the federal Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR 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 FDA's 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 FDA 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 QSR 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 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.

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 payers to contain or reduce the costs of healthcare coverage. In addition, efforts to reform the healthcare delivery system in the United States and Europe has increased pressure on healthcare providers to reduce costs, which has, in turn, increased pressure on medical device manufacturers to decrease prices charged for their products. 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.

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 product 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. 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 results.

We are currently reliant on the commercial success of our XT-8 system and its related test menu to partially fund our current operations and ePlex development programs.

We currently market our XT-8 instrument and four FDA-cleared diagnostic tests. In addition, we sell RUO tests and custom manufactured reagents. We have primarily placed our XT-8 systems with customers at no initial charge through reagent rental agreements, under which customers generally commit to purchase minimum quantities of test cartridges and reagents (consumables) over a typical period of one to three years, with a component of the cartridge and reagent price allocated to recover the instrument price. We also offer our XT-8 systems for sale. As a result, to the extent that our XT-8 system and our existing and future products are not commercially successful or are withdrawn from the market for any reason, our operating results, financial condition and critical ePlex development programs would be harmed and we may be required to seek additional funding to support our ongoing operations.

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 and national and regional reference laboratories; and
- the difficulty of establishing brand recognition and loyalty for our products.

Some hospital-based and reference laboratories may not consider adopting our XT-8 system unless we offer a broader menu of diagnostic tests or may choose not to convert from competitive products unless and until we are able to offer a sample-to-answer instrument solution, such as our ePlex instrument. 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 with our XT-8 system and its related test menu, our revenues and our ability to achieve profitability will be significantly impaired.

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 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 cyber-attacks, 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, 2016, we had net operating loss, or NOL, carryforwards available of approximately $206.9 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2035. 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 NOL carryforwards may also be limited by the issuance of common stock in the future. To the extent our use of NOL carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use NOL carryforwards. We have recorded a full valuation allowance against our net deferred tax assets.

We also had state NOL carryforwards of approximately $165.0 million as of December 31, 2016. 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 and extended the term of the lease through June 2021. 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 the 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

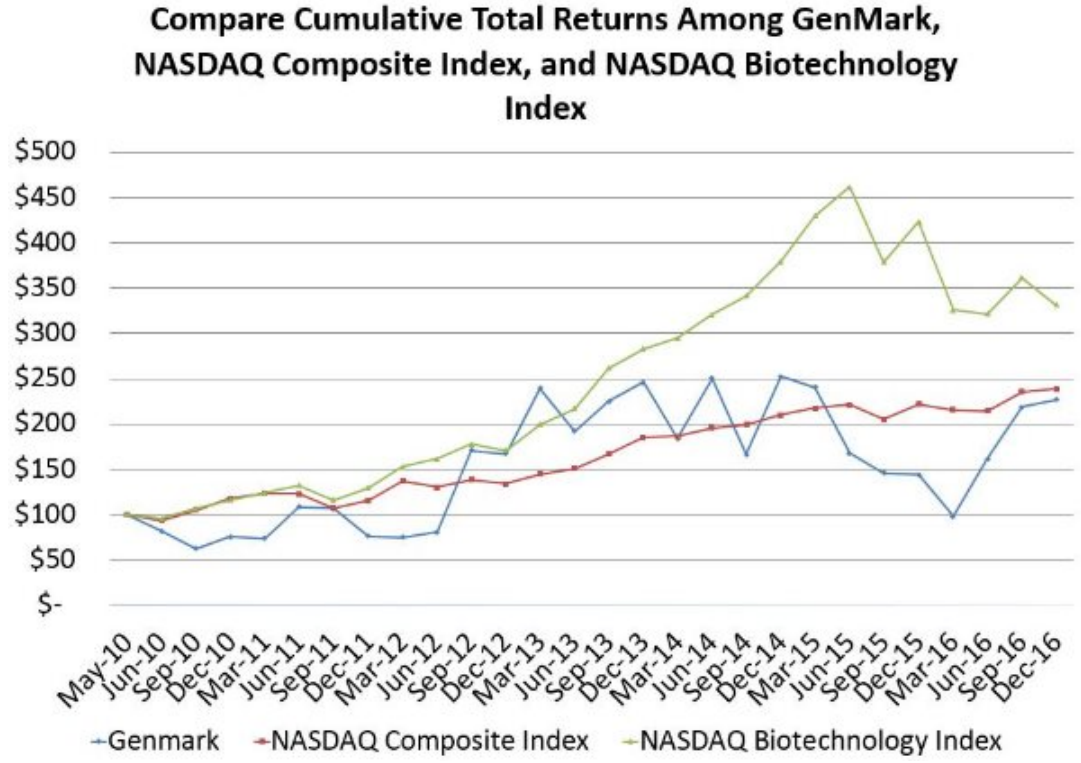
Market Information

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

	High	Low
Year Ended December 31, 2016		
First Quarter	$ 7.73	$ 4.20
Second Quarter	$ 9.48	$ 5.13
Third Quarter	$ 12.17	$ 8.03
Fourth Quarter	$ 13.29	$ 10.01
Year Ended December 31, 2015		
First Quarter	$ 14.40	$ 11.67
Second Quarter	$ 13.04	$ 8.81
Third Quarter	$ 10.55	$ 7.22
Fourth Quarter	$ 9.74	$ 4.63

Stock Performance Graph

The graph below compares the cumulative total stockholder returns on our common stock for the period indicated with the cumulative total stockholder returns on the NASDAQ Composite Index and the NASDAQ Biotechnology Index for the same period. The graph assumes that $100 was invested on May 28, 2010 in our common stock and in each index and that all dividends were reinvested. No cash dividends have been declared on our common stock. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.



Stockholders

The last reported sale price of our common stock on February 24, 2017 as reported on the NASDAQ Global Market was $11.25. As of February 24, 2017, there were 2,693 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 LSA with Solar Capital Partners 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 net loss data presented below of GenMark Diagnostics, Inc. for the years ended December 31, 2016 , 2015 , and 2014 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2016 , and 2015 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, 2013 and 2012 and the selected consolidated balance sheet data as of December 31, 2014, 2013, and 2012 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,				
	2016	**2015**	**2014**	**2013**	**2012**
Consolidated Statements of Net Loss Data:	(In thousands, except per share data)				
Revenue					
Product revenue	$ 48,914	$ 39,029	$ 30,328	$ 27,204	$ 20,211
License and other revenue	360	382	266	200	258
Total revenue	49,274	39,411	30,594	27,404	20,469
Cost of revenue	19,700	15,317	13,127	15,570	11,640
Gross profit	29,574	24,094	17,467	11,834	8,829
Operating expenses					
Sales and marketing	14,734	14,385	12,629	12,818	6,378
General and administrative	14,363	13,772	12,069	11,836	10,806
Research and development	49,458	37,472	31,823	22,060	13,536
Total operating expenses	78,555	65,629	56,521	46,714	30,720
Loss from operations	(48,981)	(41,535)	(39,054)	(34,880)	(21,891)
Other income (expense):					
Interest income (expense), net	(1,360)	(755)	224	384	(48)
Other income (expense)	(160)	133	(6)	897	(16)
Total other income (expense)	(1,520)	(622)	218	1,281	(64)
Loss before income taxes	(50,501)	(42,157)	(38,836)	(33,599)	(21,955)
Income tax expense (benefit)	100	40	(573)	44	148
Net loss	$ (50,601)	$ (42,197)	$ (38,263)	$ (33,643)	$ (22,103)
Net loss per share, basic and diluted	$ (1.15)	$ (1.00)	$ (0.93)	$ (0.95)	$ (0.84)
Weighted average number of shares outstanding, basic and diluted	44,100	42,157	41,346	35,253	26,215

	As of December 31,				
	2016	**2015**	**2014**	**2013**	**2012**
	(In thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents and marketable securities(1)(2)(3)	$ 41,566	$ 45,465	$ 70,506	$ 105,589	$ 51,250
Total assets	80,324	70,667	91,970	121,754	68,016
Long-term liabilities	15,752	11,481	1,653	2,349	2,392
Total liabilities	42,173	22,070	13,946	12,586	11,566
Accumulated deficit	(355,270)	(304,669)	(262,472)	(224,209)	(190,566)
Total stockholders' equity (1)(2)(3)	38,151	48,597	78,024	109,168	56,450

(1) In August and September 2016, we issued approximately 8.3 million shares of common stock at an average price of $9.04 per share. We raised approximately $29.1 million in net proceeds.

(2) In August 2013, we issued approximately 8.7 million shares of common stock at a price of $9.84 per share. We raised approximately $81.0 million in net proceeds.

(3) In June 2012, we issued approximately 11.5 million shares of common stock at a price of $4.20 per share. We raised approximately $45.1 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 ptc, 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 tests that aid in the diagnosis of complex medical conditions and help guide therapy decisions. 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, 2016 , 2015 , and 2014 were approximately $50.6 million , $42.2 million , and $38.3 million , respectively. As of December 31, 2016 , we had an accumulated deficit of $355.3 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 develop and commercialize our ePlex system and additional diagnostic tests, as well as to further increase our manufacturing capabilities and domestic and international commercial organization.

Our Products and Technology

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 an HCV genotyping test and associated custom manufactured reagents, as well as a 2C19 Genotyping Test, versions of which are available for use with our XT-8 instrument for research use only (RUO).

In addition, we have commercially launched in Europe our sample-to-answer ePlex instrument and RP Panel, which integrates automated nucleic acid extraction and amplification with our eSensor detection technology to enable operators using ePlex to place a raw or a minimally prepared patient sample directly into our test cartridge and obtain results without any additional steps. This sample-to-answer capability is enabled by the robust nature of our eSensor detection technology, which is not impacted to the same degree by sample impurities that we believe hinder competing technologies. We have designed our ePlex system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories. We obtained CE Mark for our ePlex system and RP Panel in June 2016, and filed 510(k) applications with the FDA for the ePlex instrument and RP Panel in December 2016. During 2017, we intend to complete the development of, CE Mark, and submit 510(k) applications to the FDA our ePlex blood culture identification (BCID) family of panels, which include a gram-positive (GP), a gram-negative (GN), and a fungal pathogen panel. In addition, we are actively evaluating the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

Revenue

Revenue from operations includes product sales, principally of our diagnostic tests. 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 three 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, including royalties on product sales. Cost of revenues also includes depreciation on revenue generating instruments that have been placed with our customers under a reagent rental agreement, cost of instruments sold to customers, amortization of licenses related to our products and other costs such as warranty, royalty and customer and product technical support. We manufacture our test cartridges in our facility and have recently invested in significant capacity for expansion. 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 tests; however, we expect gross margins related to our products will increase as production volumes, manufacturing efficiencies, improved procurement practices, instrument reliability increases and other improvements decrease costs as a percentage of sales.

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 increase as we increase our domestic and international commercial efforts to expand our customer base.

Research and Development Expenses

Research and development expenses primarily include costs associated with the development of our ePlex instrument and its 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 and equipment, costs of consumables and materials used in product development, contract research organization costs, clinical studies and facility costs. We expense all research and development costs in the periods in which they are incurred.

General and Administrative Expenses

Our general and administrative expenses include expenses related to 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 and consulting fees, and travel, 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 product sales and contractual arrangements, net of discounts and sales related taxes. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured. Where applicable, all revenue is stated net of sales taxes and trade discounts. Revenue related to royalties received from licenses is generally recognized evenly over the contractual period to which the license relates. In those cases where we bill shipping and handling costs to customers, the amounts billed are classified as other revenue.

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 is sold, revenue is generally recognized upon shipment of the unit consistent with contract terms. 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 European countries and through distributor arrangements in other European jurisdictions. The instrument price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on instrument and test cartridge sales is generally recognized upon shipment consistent with contract terms, which is when title and the risk of loss and rewards of ownership have been transferred to the customer and there are no other post-shipment obligations.

Allowance for Doubtful Accounts Receivable

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

Inventory

We value inventories at the lower of cost or net realizable value on a part-by-part basis and provide an inventory reserve for estimated obsolescence and excess inventory based upon historical turnover and assumptions about future demand for our products and market conditions. We determine excess and obsolete inventories based on an estimate of the future demand for our products within a specified time horizon, which is generally 12 months. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our revenue forecasts. If our actual demand is less than our forecast demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Property and Equipment — net

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

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

Repair and maintenance costs are expensed as incurred. During 2016, 2015 and 2014, we disposed of certain assets no longer in use with a net book value of $76,000, $153,000 and $102,000, respectively, recorded to cost of revenue, sales and marketing, research and development, or general and administrative expenses based on the asset's respective use.

Impairment of Long-Lived Assets

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

Stock-Based Compensation

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

- *Expected Term.* The expected term represents the period that our stock-based awards are expected to be outstanding and is determined by using the simplified method.
- *Expected Volatility* . Expected volatility represents the expected volatility in our stock price over the expected term of the stock option or award.
- *Expected Dividend* . The pricing models require a single expected dividend yield as an input. We assumed no dividends as we have never paid dividends and have no plans to do so.
- *Risk-Free Interest Rate* . The risk-free interest rates used in the models is based on published government rates in effect at the time of grant for periods corresponding with the expected term of the option or award.

Income Taxes

Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management’s best assessment of estimated future taxes to be paid. We file income tax returns in the United States, Switzerland, Germany, the United Kingdom, France, and various state jurisdictions. Significant judgments and estimates are required in determining our consolidated income tax expense.

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

Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future. We are not aware of any such changes that would have a material effect on our results of operations, cash flows or financial position.

We recognize tax liabilities in accordance with Accounting Standards Codification, or ASC, Topic 740 and we adjust these liabilities when our judgment changes as a result of the evaluation of new information not previously available. Due to the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from

our current estimate of the tax liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which they are determined.

Recent Accounting Pronouncements

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

Results of Operations

Comparison of Years Ended December 31, 2016 , 2015 and 2014 (tables in thousands):

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Revenue	$ 49,274	$ 39,411	$ 30,594	$ 9,863	25%	$ 8,817	29%

Our revenue consists primarily of revenue from the sale of test cartridges and reagents (consumables), with a small component from our sale of instruments and other revenue.

For the year ended December 31, 2016, our revenue grew 25%, or $9,863,000, compared to 2015. Consumables revenue during the year ended December 31, 2016 increased by 23% to $46,946,000, compared to $38,061,000 in the prior year. This increase in consumable revenue was primarily driven by increased product purchases by several key customers. Pricing changes did not have a significant impact on revenue during the current period. Additionally, during the year ended December 31, 2016, instrument revenue increased $957,000 compared to the same period of the prior year, primarily due to the sale of ePlex instruments.

For the year ended December 31, 2015, our revenue grew 29%, or $8,817,000, compared to 2014. Consumables revenue during the year ended December 31, 2015 increased by 30% to $38,061,000 compared to $29,235,000 in the prior year. This increase in consumable revenue was primarily driven by increases in our installed base of XT-8 analyzers over the prior year period. Pricing changes did not have an impact on revenue during 2015.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Cost of Revenue	$ 19,700	$ 15,317	$ 13,127	$ 4,383	29%	$ 2,190	17%
Gross Profit	$ 29,574	$ 24,094	$ 17,467	$ 5,480	23%	$ 6,627	38%

The increase in cost of revenue for the twelve months ended December 31, 2016 compared to the twelve months ended December 31, 2015 was primarily related to the increase in consumables revenue in the current year. Increases in our cost of revenue were attributable to product costs of $3,177,000, increased product warranty and support expenses of $519,000, and increased royalty expense of $431,000 corresponding to sales volume increases, less favorable manufacturing yields and variances of $235,000, and increased overhead expenses of $412,000, partially offset by decreased inventory reserve expense of $387,000. The improvement to gross profit during the year ended December 31, 2016, compared to December 31, 2015, was primarily due to increased sales of higher margin products.

The increase in cost of revenue for the twelve months ended December 31, 2015 compared to the twelve months ended December 31, 2014 was primarily related to the increase in consumables revenue during 2015. Increases in our cost of revenue in 2015 were attributable to product costs of $2,548,000 corresponding to sales volume increases, the expansion of our customer technical support group of $200,000, increased warranty reserve of $144,000, and increased royalty expense of $138,000, partially offset by greater manufacturing efficiencies of $761,000. The improvement to gross profit during the year ended December 31, 2015, compared to December 31, 2014, was primarily due to increased sales of higher margin products and a reduction in manufacturing personnel costs.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Sales and Marketing	$ 14,734	$ 14,385	$ 12,629	$ 349	2%	$ 1,756	14%

Sales and marketing expenses primarily comprise employee-related expenses for our domestic and international commercial organization, and marketing communication and trade show expenses. The increase in sales and marketing expense for the year ended December 31, 2016, compared to the year ended December 31, 2015, was primarily driven by increased marketing and trade show expense of $582,000, increased freight and postage expense of $184,000, and increased travel expenses of $112,000 incurred in connection with expanding our domestic and international commercial organization, partially offset by a decrease in employee-related expenses of $522,000.

The increase in sales and marketing expense for the year ended December 31, 2015, compared to the year ended December 31, 2014, was primarily driven by a $1,747,000 increase in employee-related expenses, including increased stock-based compensation expense of $1,187,000, incurred in connection with expanding our domestic and international commercial organization.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
General and Administrative	$ 14,363	$ 13,772	$ 12,069	$ 591	4%	$ 1,703	14%

The increase in general and administrative expense for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily driven by an increase in employee-related expenses of $536,000, an adjustment to our indirect tax accrual of $274,00, and an increase in travel-related expenses of $168,000, partially offset by a decrease in medical device tax expense of $447,000 as a result of the suspension of the excise tax in December 2015.

The increase in general and administrative expense for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to increased employee-related expenses of $1,966,000, including increased stock-based compensation expense of $1,559,000, and increased medical device tax of $447,000 as a result of higher product sales, partially offset by a $138,000 decrease in consultant and outside service costs and decreased legal expenses of $77,000.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Research and Development	$ 49,458	$ 37,472	$ 31,823	$ 11,986	32%	$ 5,649	18%

The increase in research and development expense for the year ended December 31, 2016 , compared to the year ended December 31, 2015 , was primarily driven by increased materials, equipment and consumables used in the development and expansion of our ePlex test menu totaling $10,523,000, increased employee-related expenses of $2,993,000, and increased clinical trials expense of $887,000, partially offset by reduced outside services expenditures of $3,420,000.

The increase in research and development expense for the year ended December 31, 2015 , compared to the year ended December 31, 2014 , was primarily due to increased ePlex assay development expenses of $3,993,000, increased clinical trials and quality assurance expenses of $897,000, and an increase in ePlex instrument expenses of $663,000. Overall increases in research and development expenses were attributable to employee-related expenses, clinical trials expenses, and supplies and other materials to support our ePlex system and its related test menu.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Other Income (Expense)	$ (1,520)	$ (622)	$ 218	$ (898)	144%	$ (840)	(385)%

Other income (expense) represents non-operating income and expense, including, but not limited to, earnings on cash, cash equivalents, marketable securities, and interest expense related to debt. The change in other income (expense) for the year ended December 31, 2016 , compared to the year ended December 31, 2015 , was due primarily to an increase in interest expense of $655,000 under our debt facility, and a decrease in income as a result of less interest earned on marketable securities of $217,000 in the current period.

The change in other income (expense) for the year ended December 31, 2015 , compared to the year ended December 31, 2014 , was due primarily to an increase in interest expense of $860,000 under our debt facility, a decrease in income as a result of less interest earned on marketable securities of $119,000, and an $84,000 increase in unrealized foreign currency losses as a result of our expanding international operations, partially offset by income from a one-time payment of $223,000 received from the release of escrowed proceeds related to our sale of a preferred stock investment in the fourth quarter of 2014.

	Years ended December 31,			2016 vs 2015		2015 vs 2014	
	2016	2015	2014	$ Change	% Change	$ Change	% Change
Income Tax Expense (Benefit)	$ 100	$ 40	$ (573)	$ 60	150%	$ 613	107%

Due to net losses incurred domestically, the tax provisions recorded relate to minimum tax payments in the United States. We have recorded tax liabilities related to income earned in local jurisdictions by our foreign subsidiaries. The increase in income tax expense for the year ended December 31, 2016, compared to the year ended December 31, 2015, was primarily a result of international income taxes. The increase in income tax expense for the year ended December 31, 2015 was primarily due to the expiration of the statue of limitations on uncertain tax positions resulting in the recognition of a $610,000 tax benefit in 2014.

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. At December 31, 2016 , we had $32,028,000 of working capital, including $41,566,000 in cash, cash equivalents, and marketable securities.

Cash Flows

The following table shows cash flow information for the years ended December 31, 2016 , 2015 and 2014 :

	Years Ended December 31,		
	2016	2015	2014
Cash used in operating activities	$ (35,637)	$ (31,915)	$ (29,572)
Cash provided by (used in) investing activities	(24,123)	19,321	29,417
Cash provided by financing activities	40,359	11,133	1,287
Effect of exchange rate changes on cash	(25)	(9)	—
Net increase (decrease) in cash and cash equivalents	$ (19,426)	$ (1,470)	$ 1,132

Cash flows used in operating activities

Net cash used in operating activities increased $3,722,000 to $35,637,000 for the year ended December 31, 2016, compared to $31,915,000 for the year ended December 31, 2015. The increase in cash used in operating activities was primarily due to an $8,404,000 increase in our net loss and $535,000 in lower non-cash charges primarily comprised of stock-based compensation expense, partially offset by an additional $5,217,000 cash inflow from changes in operating assets and liabilities. The main drivers in the change in operating assets and liabilities included increases in accounts payable, accrued compensation and other liabilities and increases in inventory and accounts receivable.

Net cash used in operating activities increased $2,343,000 to $31,915,000 for the year ended December 31, 2015, compared to $29,572,000 for the year ended December 31, 2014. The increase in cash used in operating activities was primarily due to a $3,934,000 increase in net loss and $4,658,000 in lower non-cash charges primarily related to less bad debt expense and impairment, partially offset by $3,067,000 of less cash outflow from changes in operating assets and liabilities.

Cash flows provided by (used in) investing activities

Net cash used in investing activities for the year ended December 31, 2016, compared to the year ended December 31, 2015, increased $43,444,000 primarily due to a $36,000,000 decrease from the maturity of short-term marketable securities, an increase in purchases of marketable securities of $11,042,000 , and increased purchase of property, plant, equipment and licenses of $4,194,000 , partially offset by a $7,792,000 increase in proceeds from the sale of marketable securities.

Net cash provided by investing activities for the year ended December 31, 2015, compared to the year ended December 31, 2014, decreased $10,096,000 primarily due to a $10,000,000 decrease from the maturity of short-term marketable securities and a $7,274,000 decrease in proceeds from the sale of marketable securities related to our sale of a preferred stock investment, partially offset by a decrease in purchases of marketable securities of $5,408,000.

Cash flows provided by financing activities

Net cash provided by financing activities increased $29,226,000 to $ 40,359,000 for the year ended December 31, 2016 , compared to $11,133,000 for the year ended December 31, 2015, primarily due to a $28,893,000 increase in net proceeds

generated from from an at-the-market equity offering described in greater detail below, and an absence of debt issuance costs of $628,000 incurred in the prior year, partially offset by a decrease in proceeds from the exercise of employee stock options of $277,000 .

Net cash provided by financing activities increased $9,846,000 to $11,133,000 for the year ended December 31, 2015, compared to $1,287,000 for the year ended December 31, 2014, primarily due to the borrowing of $10,000,000 under our debt facility and $458,000 in higher proceeds from stock option exercises, partially offset by $718,000 in costs associated with debt issuance.

We have prepared cash flow forecasts which indicate, based on our current cash resources available, that we will have sufficient resources to fund our business for at least the next 12 months. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, and expand our research and development, commercialization and manufacturing activities. Factors that could affect our capital requirements, in addition to those previously identified, include, but are not limited to:

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

Loan and Security Agreement

In January 2015, we entered into a Loan and Security Agreement, of the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other financial institutions party thereto, as lenders, pursuant to which we obtained (a) up to $35,000,000 in a series of term loans and (b) a revolving loan in the maximum amount of $5,000,000. Under the terms of the LSA, as amended, we could, subject to certain conditions, borrow:

- $10,000,000 (Term Loan A) on or before March 31, 2015, which we borrowed in March 2015;
- an additional $10,000,000 (Term Loan B), subject to our satisfaction of regulatory requirements necessary to CE Mark our ePlex system in Europe by a specified date, which we borrowed in June 2016;
- an additional $15,000,000 (Term Loan C), subject to our satisfaction of FDA 510(k) market clearance for the sale of our ePlex system in the United States by a specified date; and
- up to $5,000,000 in the form of a revolving loan, which is subject to a defined borrowing base as set forth in the LSA.

In July 2016, we entered into an amendment to the LSA pursuant to which the lenders internally reallocated certain funding commitments under the LSA between the lenders, and the parties extended the date by which the future funding requirements in respect of Term Loan C must be satisfied.

In February 2017, we entered into an amendment to the LSA pursuant to which the parties further extended the date by which the future funding requirements in respect of Term Loan C must be satisfied. In addition, the parties agreed to extend the interest-only period in respect of amounts already borrowed under Term Loan A and Term Loan B, as well as the amounts, if any, we may borrow pursuant to Term Loan C.

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, (b) the stock of all of our domestic subsidiaries, and (c) 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.

Equity Distribution Agreement

On June 14, 2016, we entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity Inc., as sales agent, or Canaccord, pursuant to which we could, at our discretion, offer and sell, from time to time, through Canaccord shares of our common stock having an aggregate offering price of up to $30.0 million. Under the Distribution Agreement, Canaccord could sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the Securities Act or any other method permitted by law, including in privately negotiated transactions.

We began sales under the Distribution Agreement in August 2016 pursuant to an effective shelf registration statement on Form S-3 previously filed with the SEC. During the three months ended September 30, 2016, we sold 3.3 million shares of our common stock, at an average per share price of $9.04, for aggregate gross proceeds of $30.0 million. We incurred $1,143,000 in related transaction costs, comprising commissions paid to Canaccord of 3.0% of the aggregate gross proceeds from each sale of shares occurring pursuant to the Distribution Agreement, or $900,000, and $243,000 in additional miscellaneous expenses.

Letter of Credit

In September 2012, we provided a $758,000 letter of credit issued by Banc of California to the landlord of our executive office facility in Carlsbad, California. This letter of credit was secured with $758,000 of restricted cash at December 31, 2016.

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, 2016 , 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)	$ 10,058	$ 1,644	$ 5,677	$ 2,143	$ 594
Licensing payment obligations	1,750	1,494	181	75	—
Instrument purchase obligations	1,278	1,309	—	—	—
Total obligations	$ 13,086	$ 4,447	$ 5,858	$ 2,218	$ 594

(1) We enter into leases in the ordinary course of business with respect to 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.

In January 2012, we entered into a lease amendment with the landlord of our Carlsbad, California executive office facility to rent an additional 22,000 square feet. The lease amendment required an additional security deposit of $22,000 and an increase in our standby letter of credit to $758,000 . We took possession of the additional space on January 1, 2013, at which time the rent increased by approximately $35,000 per month, subject to annual increases of between 3% and 4%. The term of the lease was also extended to June 30, 2021.

In August 2012, we entered into a three-year supply agreement with Leica for the purchase of our XT-8 instrument. Amounts reported in the table above reflect minimum purchase commitments under this supply agreement which we can satisfy through instrument purchases or the payment of a designated fee for each instrument we fail to purchase under the prescribed minimum amounts, subject to certain permitted exclusions.

In December 2015, we entered into a manufacturing and supply agreement with Plexus for the purchase of our ePlex instrument. Amounts reported in the table above reflect the current minimum purchase commitments under this supply agreement, which we satisfy through instrument and component part purchases.

In June 2015, we entered into a lease agreement for additional manufacturing space located in Carlsbad, California. Pursuant to the lease agreement, rent payments total $4,490,000 over the 90-month lease term.

Impact of Inflation

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

Off-Balance Sheet Arrangements

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

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, 2016 , based on current interest rates and total debt outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

Foreign Currency Exchange Risks

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

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of GenMark Diagnostics, Inc.

We have audited the accompanying consolidated balance sheets of GenMark Diagnostics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of GenMark Diagnostics, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, 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), GenMark Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2017

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

	As of December 31,	
	2016	**2015**
Current assets		
Cash and cash equivalents	$ 15,959	$ 35,385
Marketable securities	25,607	10,080
Accounts receivable, net of allowances of $2,740 and $2,727, respectively	9,048	6,847
Inventories	6,633	3,054
Prepaid expenses and other current assets	1,202	591
Total current assets	58,449	55,957
Non-current assets		
Property and equipment, net	18,268	11,396
Intangible assets, net	2,670	2,376
Restricted cash	758	758
Other long-term assets	179	180
Total assets	$ 80,324	$ 70,667
Current liabilities		
Accounts payable	$ 8,703	$ 4,376
Accrued compensation	5,650	3,861
Loan payable	7,935	(373)
Other current liabilities	4,133	2,725
Total current liabilities	26,421	10,589
Long-term liabilities		
Deferred rent	3,652	1,257
Long-term debt	11,880	9,890
Other non-current liabilities	220	334
Total liabilities	42,173	22,070
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; 46,554 and 42,551 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	4	4
Additional paid-in capital	393,322	353,233
Accumulated deficit	(355,270)	(304,669)
Accumulated other comprehensive income (loss)	95	29
Total stockholders' equity	38,151	48,597
Total liabilities and stockholders' equity	$ 80,324	$ 70,667

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,		
	2016	**2015**	**2014**
Revenue			
Product revenue	$ 48,914	$ 39,029	$ 30,328
License and other revenue	360	382	266
Total revenue	49,274	39,411	30,594
Cost of revenue	19,700	15,317	13,127
Gross profit	29,574	24,094	17,467
Operating expenses			
Sales and marketing	14,734	14,385	12,629
General and administrative	14,363	13,772	12,069
Research and development	49,458	37,472	31,823
Total operating expenses	78,555	65,629	56,521
Loss from operations	(48,981)	(41,535)	(39,054)
Other income (expense)			
Interest income	176	125	244
Interest expense	(1,536)	(880)	(20)
Other income (expense)	(160)	133	(6)
Total other income (expense)	(1,520)	(622)	218
Loss before provision for income taxes	(50,501)	(42,157)	(38,836)
Income tax expense (benefit)	100	40	(573)
Net loss	$ (50,601)	$ (42,197)	$ (38,263)
Net loss per share, basic and diluted	$ (1.15)	$ (1.00)	$ (0.93)
Weighted average number of shares outstanding basic and diluted	44,100	42,157	41,346
Other comprehensive loss			
Net loss	$ (50,601)	$ (42,197)	$ (38,263)
Foreign currency translation adjustments	77	36	—
Net unrealized gains (losses) on marketable securities, net of tax	(11)	3	(20)
Comprehensive loss	$ (50,535)	$ (42,158)	$ (38,283)

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, 2013	41,520	$ 4	$ 333,363	$ 10	$ (224,209)	$ 109,168
Stock-based compensation expense	—	—	5,796	—	—	5,796
Issuance of employee stock purchase plan shares	89	—	812	—	—	812
Restricted stock awards issued, net of cancellations	149	—	—	—	—	—
Shares issued under stock-based compensation plans	101	—	531	—	—	531
Net loss	—	—	—	—	(38,263)	(38,263)
Unrealized loss on marketable securities	—	—	—	(20)	—	(20)
Balance—December 31, 2014	41,859	4	340,502	(10)	(262,472)	78,024
Issuance of stock in lieu of accrued bonuses	105	—	863	—	—	863
Stock-based compensation expense	—	—	9,995	—	—	9,995
Issuance of employee stock purchase plan shares	122	—	884	—	—	884
Restricted stock awards issued, net of cancellations	284	—	—	—	—	—
Shares issued under stock-based compensation plans	181	—	989	—	—	989
Net loss	—	—	—	—	(42,197)	(42,197)
Foreign currency translation adjustments	—	—	—	36	—	36
Unrealized gain on marketable securities	—	—	—	3	—	3
Balance—December 31, 2015	42,551	4	353,233	29	(304,669)	48,597
Issuance of stock in lieu of accrued bonuses	28	—	364	—	—	364
Stock-based compensation expense	—	—	9,236	—	—	9,236
Issuance of employee stock purchase plan shares	138	—	921	—	—	921
Restricted stock issued, net of cancellations	421	—	—	—	—	—
Shares issued under stock-based compensation plans	99	—	712	—	—	712
Issuance of common stock, net of offering expenses	3,317	—	28,856	—	—	28,856
Net loss	—	—	—	—	(50,601)	(50,601)
Foreign currency translation adjustments	—	—	—	77	—	77
Unrealized loss on marketable securities	—	—	—	(11)	—	(11)
Balance—December 31, 2016	46,554	$ 4	$ 393,322	$ 95	$ (355,270)	$ 38,151

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2016	2015	2014
Operating activities:			
Net loss	$ (50,601)	$ (42,197)	$ (38,263)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,916	3,405	2,656
Amortization of premiums on investments	89	180	702
Amortization of deferred debt issuance costs	388	285	—
Stock-based compensation	9,236	9,995	5,796
Provision for bad debt	13	25	—
Non-cash inventory adjustments	134	594	450
Gain on sale of investment in preferred stock	(9)	(223)	—
Other non-cash adjustments	145	186	185
Changes in operating assets and liabilities:			
Accounts receivable	(2,250)	(1,983)	(2,030)
Inventories	(3,450)	(1,286)	(229)
Prepaid expenses and other assets	(613)	(36)	(184)
Accounts payable	4,105	(757)	85
Accrued compensation	2,172	(458)	1,797
Other liabilities	1,088	355	(537)
Net cash used in operating activities	(35,637)	(31,915)	(29,572)
Investing activities			
Payments for intellectual property licenses	(1,500)	(550)	(350)
Purchases of property and equipment	(7,000)	(3,756)	(5,726)
Purchases of marketable securities	(33,688)	(22,646)	(28,054)
Proceeds from sales of marketable securities	8,015	223	7,497
Maturities of marketable securities	10,050	46,050	56,050
Net cash provided by (used in) investing activities	(24,123)	19,321	29,417
Financing activities			
Proceeds from issuance of common stock	30,920	884	812
Costs incurred in conjunction with public offering	(1,143)	—	—
Principal repayment of borrowings	(40)	(22)	(56)
Costs associated with debt issuance	(90)	(718)	—
Proceeds from borrowings	10,000	10,000	—
Proceeds from stock option exercises	712	989	531
Net cash provided by financing activities	40,359	11,133	1,287
Effect of exchange rate changes on cash	(25)	(9)	—
Net increase (decrease) in cash and cash equivalents	(19,426)	(1,470)	1,132
Cash and cash equivalents at beginning of year	35,385	36,855	35,723
Cash and cash equivalents at end of year	$ 15,959	$ 35,385	$ 36,855
Non-cash investing and financing activities:			
Transfer of systems from property and equipment into inventory	$ 263	$ 225	$ 256
Property and equipment costs incurred but not paid included in accounts payable	$ 1,159	$ 146	$ 124
Intellectual property acquisition included in accrued expenses	$ —	$ 800	$ 550
Supplemental cash flow information:			
Cash paid for interest	$ 1,130	$ 572	$ 20
Cash received for interest	$ 266	$ 305	$ 244
Cash paid for income taxes, net	$ 65	$ 10	$ 24

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.

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 consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, or 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.

Basis of Presentation

The accompanying 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 $355,270,000 at December 31, 2016 . 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, restricted cash, and investments at December 31, 2016 totaled $41,566,000 . 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.

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP and applicable regulations of the Securities and Exchange Commission, or the SEC.

Principles of Consolidation

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.

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 at December 31, 2016 held as security for the Company's letter of credit with Banc of California.

Fair Value of Financial Instruments

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

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

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

Receivables

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

The allowance for doubtful accounts as of December 31, 2016 , is as follows (in thousands):

	Allowance for doubtful accounts
Balance December 31, 2014	$ 2,702
Provision for doubtful accounts	25
Balance December 31, 2015	$ 2,727
Provision for doubtful accounts	13
Balance December 31, 2016	$ 2,740

The Company has included $2,702,000 in the allowance for doubtful accounts as of December 31, 2016 and 2015 for past due amounts from its former customer, Natural Molecular Testing Corporation.

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:

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

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. PEPs are placed with customers for evaluation periods of up to three months and the Company retains title to the instruments under these arrangements. Maintenance and repair costs are expensed as incurred.

Intangible Assets

Intangible assets are comprised of licenses or sublicenses to technology covered by patents owned by third parties, and are amortized on a straight-line basis over the expected useful lives of these assets, which is generally 10 years. Amortization of licenses typically begins upon the Company obtaining access to the licensed technology and is recorded in cost of revenues for licenses supporting commercialized products. The amortization of licenses to technology supporting products in development is recorded in research and development expenses.

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, including intangible assets, by periodically evaluating the carrying value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If impairment is indicated, the Company writes down the carrying value of the asset to its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows. The Company did not recognize any impairment charges during the years ended December 31, 2016 and 2015.

Revenue Recognition

The Company recognizes revenue from product sales and contract arrangements, net of discounts and sales related taxes. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured.

The Company offers customers the choice to either purchase a system outright or to receive a system free of charge in exchange for an annual minimum purchase commitment for diagnostic test cartridges. When a system is sold, the Company generally recognizes revenue upon shipment of the unit, however, if the end user already has the instrument being purchased installed at its location, revenue is recognized when the revenue recognition terms other than delivery have been satisfied. When a system is placed free of charge under a “reagent rental” agreement, the Company retains title to the equipment and it remains capitalized on the balance sheet under property and equipment. Under reagent rental agreements, the Company’s customers pay an additional system rental fee for each test cartridge purchased which varies based on the monthly volume of test cartridges purchased. The system rental fee and diagnostic test cartridges are recognized as contingent rental payments and are included in product revenue in the Company’s consolidated financial statements.

The Company has not had significant product returns and is not contractually obligated to accept returns unless such returns are related to warranty provisions. The Company generally does not accept reagent product returns, mainly due to FDA regulations, and does not offer volume rebates or provide price protection.

The Company enters into PEP agreements pursuant to which an instrument is installed on the premises of a pre-qualified customer for the purpose of allowing the customer to evaluate the instrument’s functionality over an extended trial period. The customer is generally required to purchase a minimum quantity of reagents and, at the end of the evaluation period, must purchase or return the instrument or sign a reagent rental agreement.

Revenues related to royalties received from licenses are recognized evenly over the contractual period to which the license relates. In those cases where the Company bills shipping and handling costs to customers, the amounts billed are included in product revenue.

In 2016 and 2015, Laboratory Corporation of America, Inc. represented 27% and 17% , respectively, of the Company's total revenue. In 2014, no single customer represented more than 10% of the Company's total revenue.

Product Warranties

The Company generally offers a one -year warranty for its instruments sold to customers and up to a sixty day warranty for reagents and provides for the estimated cost of the product warranty at the time the system sale is recognized. Factors that affect the Company's warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary.

Product warranty reserve activity for the years ended December 31, 2016 , 2015 and 2014 is as follows (in thousands):

	2016	2015	2014
Beginning balance	$ 118	$ 195	$ 226
Warranty expenses incurred	(421)	(430)	(608)
Provisions	522	353	577
Ending balance	$ 219	$ 118	$ 195

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

The estimated fair value of stock granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense that approximates straight-line expense to reflect vesting as it occurs. The stock option expense is derived from the Black-Scholes Option Pricing Model that uses several judgment-based variables to calculate the expense. The market-based stock expense is derived from the Monte Carlo Simulation Valuation. The inputs utilized in the valuation of the stock-based awards include the following factors:

- *Expected Term.* Expected term represents the period that the stock-based awards are expected to be outstanding and is determined by using the simplified method.

- *Expected Volatility* . Expected volatility represents the expected volatility in the Company's stock price over the expected term of the option or market-based award and is determined by review of the Company's and similar companies' historical experience.
- *Expected Dividend* . The valuation methods required 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

During 2015, the Company established foreign subsidiaries with currencies other than the U.S. Dollar. The assets and liabilities of the Company's entities outside the U.S. are translated into U.S. Dollars based on the foreign currency exchange rates at the end of each period, while revenues and expenses are translated at weighted average exchange rates during the applicable period. Gains or losses resulting from these foreign currency translations of the Company's assets and liabilities are recorded in accumulated comprehensive loss in the consolidated balance sheets. Foreign currency translation impacts recorded in accumulated other comprehensive loss for the year ended December 31, 2016 and 2015 was $77,000 and $36,000 , respectively.

Transactions in foreign currencies were recognized using the rate of exchange prevailing at the date of the transaction. Foreign exchange losses, which are included in the accompanying consolidated statements of operations, totaled $169,000 , $91,000 and $9,000 for the years ended December 31, 2016 , 2015 and 2014 , 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 our common stock (the numerator) by the weighted average number of shares of the Company's common stock outstanding during the period (the denominator). Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. Diluted loss per share is calculated in a similar way to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the dilutive potential shares had been issued unless the effect would be anti-dilutive.

The calculations of diluted net loss per share for the years ended December 31, 2016 , 2015 and 2014 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,		
	2016	2015	2014
Options outstanding to purchase common stock	2,570	3,004	2,479
Other unvested equity awards	2,000	1,267	948
Total	4,570	4,271	3,427

Concentration of Risk

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

	December 31,	
	2016	2015
Laboratory Corporation of America, Inc.	33%	35%

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 Standard Board, or the FASB, or other standard setting bodies that the Company adopts as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In March 2016, the FASB issued Accounting Standards Update, or ASU, 2016-09, Improvements to Employee Share-Based Payment Accounting. This guidance simplifies how several aspects of share-based payments are accounted for and presented in the financial statements. This guidance is effective for the Company beginning January 1, 2017 and the Company will adopt this ASU in the first quarter of 2017. The Company has excess tax benefits for which a benefit could not be previously recognized of approximately $1,979,000 . Upon adoption, the balance of the unrecognized excess tax benefits will be reversed with the impact recorded to retained earnings, including any change to the valuation allowance as a result of adoption. Due to the full valuation allowance on the Company's U.S. deferred tax assets, the Company does not expect any impact to the financial statements as a result of this adoption.

In February 2016, the FASB issued ASU 2016-02, Leases. This ASU outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new guidance requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms of greater than 12 months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new guidance must be adopted using the modified retrospective approach and will be effective for the Company starting in the first quarter of 2019, with early adoption permitted. The Company is evaluating the effects adoption will have on its consolidated financial statements. The Company expects this adoption will result in a material increase in the assets and liabilities on our consolidated balance sheets and will likely have an immaterial impact on our consolidated statements of comprehensive loss.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, an updated standard on revenue recognition. ASU 2014-09 provides enhancements to the quality and consistency of how revenue is reported by companies while also improving comparability in the financial statements of companies reporting using International Financial Reporting Standards or U.S. GAAP. The main purpose of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration to which a company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures of revenue, provide guidance for transactions that were not previously addressed comprehensively, and improve guidance for multiple-element arrangements. In August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date, which deferred the effective date of the new revenue standard for periods beginning after December 15, 2016 to December l5, 2017, with early adoption permitted but not earlier than the original effective date. Accordingly, the updated standard is effective for the Company in the first quarter of fiscal 2018. The Company is currently evaluating the overall impact this standard will have on our consolidated financial statements, as well as the expected timing and method of adoption. Based on our preliminary assessment, the Company does not anticipate a material impact on its financial statements. The Company is continuing this assessment, which may identify other impacts.

3. Intangible Assets, net

Intangible assets as of December 31, 2016 and 2015 consisted of the following (in thousands):

	December 31, 2016			December 31, 2015		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$ 4,250	$ (1,580)	$ 2,670	$ 3,550	$ (1,174)	$ 2,376

In March 2012, the Company entered into a license agreement with Caliper Life Sciences Inc., or Caliper, pursuant to which the Company obtained a non-exclusive license under Caliper's microfluidics patent portfolio. In consideration for the license, the Company agreed to pay Caliper $400,000 in up-front payments recorded as an intangible asset on the Company's balance sheet plus certain sales-based milestone payments, as well as a royalty on the sale of certain products. As part of the agreement, the Company obtained an unconditional release from any and all claims based upon any alleged infringement of the licensed patents prior to the effective date of the agreement. The Company met sales-based milestones in March 2013, March 2014 and August 2015 triggering the payment of $450,000 , $550,000 , and $800,000 , respectively, which were made after the fiscal year during which the respective milestone was achieved.

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. Pursuant to the agreement, as amended, the Company will be obligated to pay to ALL a royalty consisting of a low- to mid-single digit percent of net sales of designated licensed products containing ALL components. The Company met certain milestones in August 2013, June 2014 and September 2016 resulting in the payment of $200,000 , $350,000 and $700,000 , respectively, to ALL.

Intellectual property licenses had a weighted average remaining amortization period of 5.40 years as of December 31, 2016 . Amortization expense for intangible assets amounted to $406,000 , $294,000 and $227,000 for the years ended December 31, 2016 , 2015 and 2014 , respectively. Estimated future amortization expense for these licenses is as follows (in thousands):

Years Ending December 31,	Future Amortization Expense
2017	$ 497
2018	497
2019	497
2020	497
2021	497
Thereafter	185
Total	$ 2,670

4. Stockholders' Equity

On June 14, 2016, the Company entered into an Equity Distribution Agreement, or the Distribution Agreement, with Canaccord Genuity Inc., as sales agent, or Canaccord, pursuant to which the Company could, at its discretion, offer and sell, from time to time, through Canaccord shares of its common stock having an aggregate offering price of up to $30,000,000 . Under the Distribution Agreement, Canaccord could sell shares by any method deemed to be an "at-the-market" offering as defined in Rule 415 under the Securities Act or any other method permitted by law, including in privately negotiated transactions.

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

5. Stock-Based Compensation

In 2010, the Company adopted the 2010 Equity Incentive Plan, or the 2010 Plan, which provides for the grant of incentive and nonstatutory stock options, restricted stock, stock appreciation rights, restricted stock units, restricted stock bonuses and other stock-based awards. Employee participation in the 2010 Plan is at the discretion of the compensation committee of the board of directors of the Company. 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 generally vest over a period of between one and four years.

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

Stock options are generally exercisable for a period up to 10 years after grant and are forfeited if employment is terminated before the options vest. As of December 31, 2016 , there were 79,455 shares available for future grant of awards under the 2010 Plan.

The following table summarizes stock option activity during the year ended December 31, 2016 :

	Number of shares		Weighted average exercise price
Outstanding at December 31, 2015	3,004,011	$	9.74
Granted	5,000	$	4.70
Exercised	(98,941)	$	7.20
Forfeitures	(340,520)	$	11.96
Outstanding at December 31, 2016	2,569,550	$	9.53
Vested and expected to vest at December 31, 2016	2,490,256	$	9.45
Exercisable at December 31, 2016	1,937,739	$	8.75

The weighted average fair value of options granted during the years ended December 31, 2016 , 2015 and 2014 was $2.27 , $6.02 and $7.45 per share, respectively. Options that were exercisable as of December 31, 2016 had a remaining weighted average contractual term of 5.67 years and an aggregate intrinsic value of $7,036,000 . As of December 31, 2016 , there was $3,323,000 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 1.57 years. The intrinsic value of options exercised during the years ended December 31, 2016 , 2015 and 2014 was $896,000 , $938,000 and $584,000 , respectively. As of December 31, 2016 , there were 2,569,550 stock options outstanding, which had a remaining weighted average contractual term of 6.20 years and an aggregate intrinsic value of $7,532,000 .

Valuation of Stock-Based Awards

The assumptions used in the valuation of stock-based awards for the years ended December 31, 2016 , 2015 and 2014 , are summarized in the following table:

	Years Ended December 31,		
	2016	2015	2014
Expected volatility (%)	51%	49%	69%
Expected life (years)	5.90	6.06	6.08
Risk free rate (%)	1.35%	1.67%	1.82%
Expected dividend yield (%)	—%	—%	—%

Restricted Stock Awards and Units

In March 2013, the Company transitioned to granting restricted stock units under the 2010 Plan in lieu of granting restricted stock awards. The Company's restricted stock activity for the year ended December 31, 2016 was as follows:

	Restricted Stock Awards		Restricted Stock Units	
	Number of shares	Weighted Average Grant Date Fair Value	Number of shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2015	32,837	$ 5.00	934,977	$ 12.66
Granted	—	$ —	1,580,273	$ 5.80
Vested	(32,369)	$ 4.91	(444,365)	$ 11.79
Forfeitures	(312)	$ 11.19	(304,762)	$ 7.65
Unvested at December 31, 2016	156	$ 11.19	1,766,123	$ 7.18

Restricted stock awards or units may be granted at the discretion of the compensation committee of the board of directors under the 2010 Plan in connection with the hiring or retention of personnel and are subject to certain conditions. Restrictions expire at certain dates after the grant date in accordance with specific provisions in the applicable award agreement.

As of December 31, 2016 , there was $1,000 of unrecognized compensation cost related to restricted stock awards, which is expected to be recognized over a weighted average-period of 0.04 years. The total fair value of restricted stock awards that vested during the years ended December 31, 2016 , 2015 and 2014 was $190,000 , $580,000 and $3,466,000 , respectively.

As of December 31, 2016 , there was $8,509,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 2.80 years. The total fair value of restricted stock units that vested during the years ended December 31, 2016 , 2015 and 2014 was $3,192,000 , $ 4,457,000 and $2,121,000 , respectively.

The Company issued market-based stock units in February 2015 and February 2016, which may result in the recipient receiving shares of stock equal to up to 200% of the target number of units granted. The vesting and issuance of Company stock 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, 2016 , there was $781,000 of unrecognized stock-based compensation expense related to these awards, which is expected to be recognized over a weighted average period of 1.75 years. The total fair value of market-stock units that vested during the years ended December 31, 2016 and 2015 was $ 2,433,000 and $29,000 , respectively. The Company's market-based stock unit activity for the year ended December 31, 2016 was as follows:

	Market-Based Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2015	136,730	18.07
Units granted	335,253	4.94
Vested	(192,941)	8.01
Cancelled	(56,269)	9.81
Unvested at December 31, 2016	222,773	7.34

The fair value of these market-based stock units was estimated on the date of grant using the Monte Carlo Simulation Valuation Model, which estimates the potential outcome of achieving the market condition based on simulated future stock prices, with the following assumptions for the year ended December 31, 2016 :

	2016	2015
Expected volatility	49%	45%
Risk-free interest rate	0.90%	1.10%
Expected dividend	—%	—%
Weighted average fair value	$ 4.94	$ 18.07

The Company granted 43,200 performance-based restricted stock units in March 2014 with a grant date fair value of $12.30 per share. The vesting and issuance of Company stock pursuant to these awards depends on obtaining regulatory clearance of a designated number of ePlex products within a defined time. Stock-based compensation expense for performance-based awards is recognized when it is probable that the applicable performance criteria will be satisfied. The probability of achieving the relevant performance criteria is evaluated on a quarterly basis. On December 31, 2014 , 10,800 units were earned and vested with a total fair value of $147,000 . On each of December 31, 2016 and 2015 , 10,800 units were forfeited and cancelled as the related performance metrics were not achieved by such dates. As of December 31, 2016 , there was $133,000 in unrecognized stock-based compensation expense related to the remaining unvested awards.

Employee Stock Purchase Plan

Following the adoption of the ESPP by the Company’s board of directors in March 2013, the Company's stockholders approved the ESPP in May 2013 at the Company's Annual Meeting of Stockholders. A total of 650,000 shares of the Company’s common stock are reserved for issuance under the ESPP, which permits eligible employees to purchase common stock at a discount through payroll deductions.

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, 2016 , there were 267,839 shares of common stock available for issuance under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation. As a result, stock-based compensation expense related to the ESPP, calculated using the Black-Scholes model at the beginning of each six-month offering period, has been recorded during the year ended December 31, 2016 .

A summary of ESPP activity for the years ended December 31, 2016 and 2015 is as follows (in thousands, except share, and per share data):

	Year Ended December 31,	
	2016	2015
Shares issued	138,058	122,245
Weighted average fair value of shares issued	$ 6.67	$ 7.22
Employee purchases	$ 921	$ 884

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,		
	2016	2015	2014
Cost of revenue	$ 258	$ 209	$ 73
Sales and marketing	2,329	3,050	1,848
Research and development	2,482	2,498	1,194
General and administrative	4,167	4,238	2,681
Stock-based compensation expense	$ 9,236	$ 9,995	$ 5,796

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, 2016 , 2015 and 2014 , respectively.

6. Income Taxes

The Company's income (loss) before provision (benefit) for income taxes for the years ended December 31, 2016, 2015, and 2014, respectively, was generated in the following jurisdictions (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Domestic	$ (50,651)	$ (42,221)	$ (37,766)
Foreign	150	64	(1,070)
Worldwide Income (Loss)	$ (50,501)	$ (42,157)	$ (38,836)

The components of income tax expense (benefit) were as follows for the years ended December 31, 2016 , 2015 , and 2014 , respectively (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Current expense:			
U.S. federal	$ (10)	$ —	$ —
State	31	25	(573)
Foreign (non-U.S. entities)	70	20	—
Total current expense (benefit)	$ 91	$ 45	$ (573)
Deferred expense (benefit):			
U.S. Federal	$ 4	$ —	$ —
State	1	—	—
Total deferred expense (benefit)	$ 5	$ —	$ —

The components of net deferred income taxes consisted of the following at December 31, 2016 and 2015 , respectively (in thousands):

	As of December 31,	
	2016	2015
Deferred income tax assets:		
NOL and credit carryforwards	$ 74,375	$ 59,907
Compensation accruals	4,660	3,952
Accruals and reserves	3,437	2,201
State tax provision	8	8
Inventory adjustments	996	559
Intangible assets	645	361
Other	144	5
Subtotal: deferred tax assets	84,265	66,993
Valuation allowance	(82,481)	(66,211)
Total deferred tax assets	1,784	782
Deferred income tax liabilities:		
Depreciation	(1,784)	(782)
Subtotal: deferred tax liabilities	(1,784)	(782)
Net deferred tax assets	$ —	$ —

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, 2016 , 2015 , and 2014 , respectively, as follows:

	Years Ended December 31,		
	2016	2015	2014
U.S. Federal statutory income tax rate	34.0 %	34.0 %	34.0 %
Permanent differences	(0.3)%	(0.1)%	(0.3)%
State taxes	2.3 %	2.4 %	2.6 %
Executive compensation limitation	(0.1)%	(0.8)%	(0.7)%
Stock-based compensation	(3.5)%	(1.4)%	(1.5)%
Other	(0.4)%	2.1 %	0.3 %
Valuation allowance	(32.2)%	(36.9)%	(32.9)%
Total tax provision	(0.2)%	(0.7)%	1.5 %

The Company had federal net operating loss (NOL) carryforwards available of approximately $206,900,000 as of December 31, 2016 after consideration of limitations under Section 382 of the Internal Revenue Code, or Section 382, as further described below. Additionally, the Company had state NOL carryforwards available of $165,000,000 as of December 31, 2016 . These federal and state NOLs may be used to offset future taxable income and will begin to expire in 2025 and 2017, respectively.

Of the $206,900,000 and $165,000,000 of federal and state NOL carryforwards at December 31, 2016 , $5,402,000 represents excess tax benefits related to equity compensation which will result in an increase in equity if and when such excess benefits are ultimately realized.

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, 2016. As a result of this assessment, the Company determined that it experienced multiple ownership changes through 2016 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, 2016 . 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, 2016 , a valuation allowance of $82,481,000 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.

The following table summarizes the changes to unrecognized tax benefits for the years ended December 31, 2016 , 2015 and 2014 , respectively (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Beginning balance of unrecognized tax benefits	$ —	$ —	$ 382
Lapses in the statute of limitations	—	—	(382)
Ending balance of unrecognized tax benefits	$ —	$ —	$ —

At December 31, 2016 and December 31, 2015 , 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 returns since inception are subject to examination due to the carryover of net operating losses. As of December 31, 2016 , the Company’s tax years from 2011 through 2012 are subject to examination by the United Kingdom tax authorities. The statute of limitations for the assessment and collection of income taxes related to other foreign tax returns varies by country. In the foreign countries where the Company has operations, these time periods generally range from three to five years after the year for which the tax return is due or the tax is assessed.

7. Commitments and Contingencies

Leases

The Company has lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged were $1,871,000 , $1,233,000 and $1,147,000 for the years ended December 31, 2016 , 2015 , and 2014 , respectively. Pursuant to the Company’s lease agreements, a portion of the monthly rent has been deferred. The balance deferred at December 31, 2016 and 2015 was $4,097,000 and $1,445,000 , respectively.

Annual future minimum obligations for leases as of December 31, 2016 are as follows (in thousands):

Years Ending December 31,	Amount
2017	$ 1,644
2018	1,792
2019	1,913
2020	1,972
2021	1,372
Thereafter	1,365
Total minimum lease payments	$ 10,058

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, 2016 and 2015 comprised the following (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 2,171	$ 1,147
Work-in-process	1,488	693
Finished goods	2,974	1,214
	$ 6,633	$ 3,054

9. Property and Equipment, net

Property and equipment comprised the following as of December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Property and equipment—at cost:		
Plant and machinery	$ 10,145	$ 7,728
Instruments	9,869	8,195
Office equipment	1,714	1,526
Leasehold improvements	10,100	4,311
Total property and equipment—at cost	31,828	21,760
Less accumulated depreciation	(13,560)	(10,364)
Property and equipment, net	$ 18,268	$ 11,396

Depreciation expense was $3,510,000 , $3,112,000 and $2,429,000 for the years ended December 31, 2016 , 2015 and 2014 , respectively. During the years ended December 31, 2016 , 2015 and 2014 , the Company disposed of certain assets no longer in use with a net book value of $76,000 , $153,000 , and $102,000 , 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, 2016 and 2015 , long-term debt consisted of the following (in thousands):

	December 31, 2016	December 31, 2015
Term Loans		
Term Loan A - 6.9% principal	$ 10,000	$ 10,000
Term Loan B - 6.9% principal	10,000	—
Final fee obligation	400	400
Unamortized issuance costs	(585)	(883)
Total debt, net	19,815	9,517
Current portion of long-term debt	(7,935)	373
Long-term debt	$ 11,880	$ 9,890

Term Loans

In January 2015, the Company entered into a Loan and Security Agreement, or the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other financial institutions party thereto, as lenders, pursuant to which the Company obtained (a) up to $35,000,000 in a series of term loans and (b) a revolving loan in the maximum amount of $5,000,000 . Under the terms of the LSA, the Company may, subject to certain conditions, borrow:

- $10,000,000 on or before March 31, 2015, or Term Loan A;
- an additional $10,000,000 , or Term Loan B, subject to the Company's satisfaction of regulatory requirements necessary to CE Mark its ePlex system in Europe by a specified date; and
- an additional $15,000,000 , or Term Loan C, and together with Term Loan A and Term Loan B, the Term Loans, subject to the Company's satisfaction of FDA 510(k) market clearance for the sale of the Company's ePlex system in the United States by a specified date.

The Company borrowed $10,000,000 on each of March 27, 2015 and June 10, 2016 pursuant to Term Loan A and Term Loan B, respectively. The Term Loans will accrue interest at a rate equal to (a) the greater of 1.00% or the 3-year treasury rate in effect at the time of funding, plus (b) an applicable margin between 4.95% and 5.90% per annum. The Company is only required to make interest payments on amounts borrowed pursuant to the Term Loans from the applicable funding date until March 1, 2017 , or the Interest Only Period. Following the Interest Only Period, monthly installments of principal and interest under the Term Loans will be due until the original principal amount and applicable interest is fully repaid by January 12, 2019 , or the Maturity Date. Interest expense recognized on the Term Loans for the years ended December 31, 2016 and 2015 totaled $1,184,000 and $611,000 , respectively, for the stated interest and final fee accrual.

In July 2016, the Company entered into an amendment to the LSA pursuant to which the lenders reallocated certain funding commitments under the LSA between the lenders, and the parties extended the date by which the future funding requirements in respect of Term Loan C must be satisfied.

Under the LSA, the Company is required to comply with certain affirmative and negative covenants, including, without limitation, delivering reports and notices relating to the Company's financial condition and certain regulatory events and intellectual property matters, as well as limiting the creation of liens, the incurrence of indebtedness, and the making of certain investments, payments and acquisitions, other than as specifically permitted by the LSA. As of December 31, 2016 , the Company was in compliance with all covenants under the LSA.

Revolving Loan

Pursuant to the LSA, the Company may borrow up to $5,000,000 under the revolving loan facility. Borrowings under the revolving loan will accrue interest at a rate equal to (a) the greater of 1.25% per annum or a base rate as determined by a three-month LIBOR-based formula, plus (b) an applicable margin between 2.95% and 3.95% based on certain criteria as set forth in the LSA. All principal and interest outstanding under the revolving loan is due and payable on the Maturity Date. Following the funding of Term Loan A, the Company is required to pay a commitment fee equal to 0.75% per annum of the amounts made available but unborrowed under the revolving loan. As of December 31, 2016 , the Company had not borrowed any amounts pursuant the revolving loan facility. Interest expense recognized for the unused revolving loan facility fee for the years ended December 31, 2016 and 2015 was $42,000 and $34,000 , respectively.

Debt Issuance Costs

As of December 31, 2016 and December 31, 2015, the Company had $585,000 and $883,000 , respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt.

For the twelve months ended December 31, 2016 and 2015 , amortization of debt issuance costs was $298,000 and $208,000 , respectively, which was included in interest expense in the Company's unaudited condensed 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, 2016 .

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 may make matching contributions under the 401(k) plan; however, the Company has not made any such contributions to date.

12. Other current liabilities

Other current liabilities as of December 31, 2016 and 2015 consisted of the following (in thousands):

	December 31,	
	2016	2015
Accrued royalties	$ 949	$ 1,608
Accrued warranties	219	118
Accrued tenant improvements	789	—
Deferred revenue	658	267
Other accrued liabilities	1,518	732
Total	$ 4,133	$ 2,725

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, 2016 and 2015 , respectively, (in thousands):

	December 31, 2016			
	Quotes Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market funds (cash equivalents)	$ 556	$ —	$ —	$ 556
Corporate notes and bonds	—	18,821	—	18,821
U.S. government and agency securities	—	3,503	—	3,503
Commercial paper	—	3,283	—	3,283
	$ 556	$ 25,607	$ —	$ 26,163

	December 31, 2015			
	Quotes Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market funds (cash equivalents)	$ 22,128	$ —	$ —	$ 22,128
Corporate notes and bonds	—	8,483	—	8,483
U.S. government and agency securities	—	799	—	799
Commercial paper	—	798	—	798
	$ 22,128	$ 10,080	$ —	$ 32,208

At December 31, 2016 , 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. Investments

The following table summarizes the Company's available-for-sale investments at December 31, 2016 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 18,846	$ —	$ (25)	$ 18,821
U.S. government and agency securities	3,506	—	(3)	3,503
Commercial Paper	3,283	—	—	3,283
Total	$ 25,635	$ —	$ (28)	$ 25,607

During 2013, the Company sold its preferred stock investment in ALL in connection with ALL's acquisition by Illumina, Inc., resulting in a $1,392,000 realized gain. Additionally, in 2016 and 2015 the Company received an additional $9,000 and $223,000 , respectively, related to the release of escrowed proceeds.

The following table summarizes the maturities of the Company's available-for-sale securities at December 31, 2016 (in thousands):

	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 25,635	$ 25,607
Due after one year through two years	—	—
Total	$ 25,635	$ 25,607

15. Quarterly financial data (unaudited)

	Year Ended December 31, 2016 (In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 11,064	$ 12,512	$ 10,813	$ 14,885
Gross profit	$ 6,689	$ 7,792	$ 6,451	$ 8,642
Loss from operations	$ (12,708)	$ (12,588)	$ (11,627)	$ (12,058)
Net loss	$ (12,958)	$ (12,907)	$ (12,058)	$ (12,678)
Per share data:				
Net loss per common share—basic and diluted	$ (0.30)	$ (0.30)	$ (0.27)	$ (0.27)

	Year Ended December 31, 2015 (In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ 10,107	$ 7,646	$ 8,472	$ 13,186
Gross profit	$ 6,116	$ 4,360	$ 5,120	$ 8,498
Loss from operations	$ (10,027)	$ (11,930)	$ (11,117)	$ (8,461)
Net loss	$ (9,869)	$ (12,152)	$ (11,394)	$ (8,782)
Per share data:				
Net loss per common share—basic and diluted	$ (0.24)	$ (0.29)	$ (0.27)	$ (0.21)

16. Subsequent events

The Company has completed an evaluation of all subsequent events through the issuance date of these consolidated financial statements and the following represents subsequent events for disclosure.

On February 27, 2017 the Company entered into a second amendment to the LSA with Solar Capital Partners and certain other financial institutions party thereto, as lenders, pursuant to which the parties extended the date by which the future funding requirements in respect of Term Loan C must be satisfied. In addition, the parties agreed to extend the Interest-Only Period in respect of amounts already borrowed under Term Loan A and Term Loan B, and the amount, if any, borrowed pursuant to Term Loan C, until June 1, 2017 . The parties also agreed that the Company has the option to further extend the Interest-Only Period until August 1, 2017 , and subsequently to March 1, 2018 , subject in each case to the satisfaction of certain conditions.

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, 2016 , 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, 2016 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, 2016 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, 2016 .

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2016 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

The Board of Directors and Stockholders of GenMark Diagnostics, Inc.

We have audited GenMark Diagnostics, Inc.'s internal control over financial reporting as of December 31, 2016, 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). GenMark Diagnostics, Inc.'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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, GenMark Diagnostics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2016 consolidated financial statements of GenMark Diagnostics, Inc. and our report dated February 28, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2017

Item 9B. OTHER INFORMATION

On February 27, 2017, we entered into a second amendment to the LSA with Solar Capital Partners and certain other financial institutions party thereto, as lenders, pursuant to which the parties extended the date by which the future funding requirements in respect of Term Loan C must be satisfied. In addition, the parties agreed to extend the interest-only period in respect of amounts already borrowed under Term Loan A and Term Loan B, and the amount, if any, borrowed pursuant to Term Loan C (the "Interest-Only Period"), until June 1, 2017. The parties also agreed that we have the option to further extend the Interest-Only Period until August 1, 2017, and subsequently to March 1, 2018, subject in each case to the satisfaction of certain conditions.

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 2017 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 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:

   Report of Independent Registered Public Accounting Firm

   Consolidated Balance Sheets at December 31, 2016 and 2015

   Consolidated Statements of Comprehensive Loss for the years ended December 31, 2016 , 2015 and 2014

   Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016 , 2015 and 2014

   Consolidated Statements of Cash Flows for the years ended December 31, 2016 , 2015 and 2014

   Notes to Consolidated Financial Statements

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.

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

(b) Exhibits.

The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

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 February 28, 2017 .

GENMARK DIAGNOSTICS, INC.

By: /s/ H ANY M ASSARANY

Name: **Hany Massarany**

Title: **Chief Executive Officer, President and Director (principal executive officer)**

February 28, 2017

By: /s/ SCOTT MENDEL

Name: **Scott Mendel**

Title: **Chief Financial Officer (principal financial and accounting officer)**

February 28, 2017

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hany Massarany and Scott Mendel, 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 / H ANY M ASSARANY **Hany Massarany**	President, Chief Executive Officer and Director (principal executive officer)	2/28/2017
/S/ SCOTT MENDEL **Scott Mendel**	Chief Financial Officer (principal financial and accounting officer)	2/28/2017
/ S / J AMES F OX **James Fox**	Chairman of the Board	2/28/2017
/ S / D ARYL J. F AULKNER **Daryl J. Faulkner**	Director	2/28/2017
/ S / K EVIN C. O'B OYLE **Kevin C. O'Boyle**	Director	2/28/2017
/ S / MICHAEL S. KAGNOFF **Michael S. Kagnoff**	Director	2/28/2017
/s/ LISA M. GILES **Lisa M. Giles**	Director	2/28/2017

EXHIBIT INDEX

Exhibit	Description
3.1	Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
3.2	Amended and Restated By-Laws (incorporated by reference to our Current Report on 8-K filed on October 31, 2014).
10.1	Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 8, 2010 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
10.2	Settlement and Release Agreement and First Amendment to Lease between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc., dated July 1, 2010 (incorporated by reference herein form our Form 10-K as filed with the SEC on March 14, 2013).
10.3	Settlement and Release Agreement and Second Amendment to Lease, dated January 19, 2012, by and between the Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (incorporated by reference to our Annual Report on Form 10-K filed with the Commission on March 21, 2012).
10.4	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).
10.5	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). †
10.6	Amended and Restated Chemically Modified Enzymes Kit Patent License Agreement by and between Roche Molecular Systems, Inc., F. Hoffman-La Roche Ltd., and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 27, 2008 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 21, 2010). †
10.7	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	XT-8 Instrument Supply Agreement, dated August 3, 2012, by and between Leica Biosystems Melbourne Pty Ltd 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).†

Exhibit	Description
10.15	Manufacturing and Supply Agreement, dated December 15, 2015, by and between Plexus Corp. and Clinical Micro Sensors, Inc. d.b.a GenMark Diagnostics, Inc. + ✓
10.16	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)*
10.17	The GenMark Diagnostics, Inc. 2015 Bonus Plan (incorporated by reference herein to our Form 8-K as filed with the SEC on February 25, 2015).*
10.18	The GenMark Diagnostics, Inc. 2016 Bonus Plan (incorporated by reference herein to our Form 8-K as filed with the SEC on February 24, 2016).*
10.19	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).*
10.20	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).*
10.21	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010).*
10.22	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).*
10.23	Form of Amendment of Restricted Stock, Restricted Stock Unit and/or Stock Option Agreement(s). * ✓
10.24	GenMark Diagnostics, Inc. 2013 Employee Stock Purchase Plan (incorporated by reference to our Definitive Proxy Statement on Schedule 14A filed with the Commission on April 5, 2013).*
10.25	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).*
10.26	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).*
10.27	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).*
10.28	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).*
10.29	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).*
10.30	Executive Employment Agreement dated April 13, 2010 by and between Osmetech Molecular Diagnostics and Jennifer Williams (incorporated by reference herein from our Form 10-K as filed with the SEC on March 14, 2013).*
10.31	Executive Employment Agreement dated October 12, 2012 by and between GenMark Diagnostics, Inc. and Eric Stier. * ✓
10.32	Equity Distribution Agreement dated June 14, 2016 by and between GenMark Diagnostics, Inc. and Canaccord Genuity Inc. (incorporated by reference herein from our Form 10-Q as filed with the SEC on July 28, 2016).
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 ✓

Exhibit	Description
24.1	Power of Attorney (included on the signature page hereto). ✓
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. ✓
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. ✓
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. ✓
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. ✓
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.

✓ Included in this filing.

† Confidential treatment has been granted with respect to certain portions of this exhibit.

+ GenMark has requested confidential treatment with respect to certain portions of this exhibit.

Exhibit 10.15

MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (this " **Agreement** ") is effective as of December 15, 2015 (the " **Effective Date** ") and is made by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (" **GenMark** "), a Delaware corporation with its principal place of business at 5964 La Place Court, Carlsbad, California 92008, and Plexus Corp. (" **Plexus** "), a Wisconsin corporation with its principal place of business at One Plexus Way, Neenah, Wisconsin 54956.

RECITALS

WHEREAS , GenMark is engaged in the business of designing, developing and marketing molecular diagnostic instruments, consumables assays, and other products;

WHEREAS , Plexus has expertise in the design, development and manufacture of complex diagnostic instruments; and

WHEREAS , GenMark has requested that Plexus manufacture and supply the Products (as hereinafter defined) on the terms and the conditions set forth herein.

AGREEMENT

NOW, THEREFORE , in consideration of the mutual promises, covenants and agreements herein set forth, and for other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE I
DEFINITIONS

Capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning set forth below.

1.1 " **Affiliate** " means, with respect to a party, any Person that directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a party. For this purpose, control of a Person that is a corporation or other business entity shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in, or a fifty percent (50%) or greater interest in the equity of, such corporation or other business entity.

1.2 " **Applicable Standards** " means, collectively, (a) the applicable requirements as described in the Manufacturing Documents, (b) all applicable laws and regulations, including, but not limited to, the Federal Food, Drug and Cosmetics Act, as amended, cGMP, and the European Medical Device Directive 93/42/EEC, (c) all applicable environmental, health, and safety laws; and (d) ISO 13485 and 9001.

1.3 " **Base** " means a computer and display unit to which between one (1) and four (4) Towers may be attached to operate GenMark's integrated, fully-automated molecular diagnostics ePlex™ instrument system, as more fully described in the Specifications.

1.4 " **Base System** " means an integrated, fully-automated molecular diagnostics ePlex™ instrument system comprising one (1) Base, two (2) Towers, and twelve (12) Bays, as more fully described in the Specifications.

1.5 " **Bay** " means each of six (6) removable, autonomous processing units which can accept a consumable cartridge that contains the reagents and instructions for a diagnostic test, as more fully described in the Specifications.

1.6 " **Bill of Materials** " means the list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture the Products, in each case as set forth in the Specifications.

1.7 " **cGMP** " means current good manufacturing practices, including, without limitation, the FDA's Quality System Regulations, pursuant to Title 21 of the United States Code of Federal Regulations, Part 820, as applicable to the manufacture of a medical device.

1.8 " **Change Control** " means a set of secure processes and procedures that are used to track and document versions of Product documentation that satisfies all requirements of the Applicable Standards for the manufacture of Products by Plexus

under this Agreement, which processes and procedures shall include a requirement for prior written approval by GenMark of all changes or improvements to the Product.

1.9 " **FCA** " means "Free Carrier (named place of destination)", as that expression is defined in Incoterms 2010, ICC Publishing S.A.

1.10 " **Facility** " means Plexus' manufacturing facility located at 2400 Millbrook Dr., Buffalo Grove, Illinois 60089, which shall be used to manufacture and produce Products for GenMark hereunder, or such other facility at which Products are manufactured as the parties may mutually agree in writing from time to time during the term of this Agreement.

1.11 Reserved.

1.12 " **FDA** " means the United States Food and Drug Administration or any successor agency thereof.

1.13 Reserved.

1.14 " **GenMark Equipment** " means the equipment, test fixtures, molds, devices, tools and other apparatuses located at the Facility and used to manufacture and/or test Products hereunder which are owned by GenMark, as further described in Section 4.1 hereto.

1.15 " **GenMark Intellectual Property Rights** " means all Intellectual Property Rights owned or controlled by GenMark as of the Effective Date or during the term of this Agreement.

1.16 " **Governmental Authority** " means any country, including any political subdivision, court, instrumentality, or agency thereof, and any other federal, state, or public authority, domestic or foreign, exercising governmental powers and having jurisdiction, and all statutes, laws, ordinances, regulations, orders, decrees, permits, writs, processes and rules issued thereby which may be applicable to the parties' performance under this Agreement.

1.17 An " **Insolvency Event** shall be deemed to have occurred with respect to a party if such party: (a) is unable to pay its debts as such debts become due; (b) makes a general assignment for the benefit of creditors; (c) has a petition in bankruptcy or a suit seeking reorganization, liquidation, dissolution, or similar relief filed against it; (d) files or permits the filing of any petition or answer seeking to adjudicate itself bankrupt or insolvent, or seeking for itself any liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of such party or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking or consenting to the appointment of a trustee, custodian, receiver, liquidator or other similar official for itself or for any substantial part of its property; or (e) takes any corporate action to authorize any of the foregoing actions.

1.18 " **Intellectual Property Rights** " means, collectively, all of the following intangible legal rights, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: (a) inventions, patents, patent disclosures, patent rights, including any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, utility models, industrial designs and design patents or any extensions thereof; (b) rights associated with works of authorship, including, without limitation, copyrights, copyright applications and copyright registrations; (c) rights in trademarks, trademark registrations and applications therefor, trade names, service marks, service names, logos, or trade dress; (d) rights relating to the protection of formulae, trade secrets, know-how and Confidential Information; and (e) all other intellectual or proprietary rights.

1.19 **"Manufacturing Documents** " means, collectively, the Specifications, the Bill of Materials, the Testing Criteria, the Quality Agreement, and such other manufacturing and quality assurance documentation setting forth the requirements in respect of the manufacture, storage, shipping, labelling, testing, supply, release and acceptance of Products hereunder.

1.20 " **Manufacturing Instructions** " means the manufacturing instructions prepared by the parties on behalf of GenMark, for the manufacture of the Products, as the same may be amended from time to time by written agreement of the parties during the term of this Agreement.

1.21 **"Material** " means, collectively, all raw materials, items on the Bill of Materials, packaging materials, labeling materials and other materials required to manufacture and supply the Products to GenMark in accordance with the Manufacturing Documents.

1.22 " **Person** " means any natural person, corporation, firm, business trust, joint venture, association, organization, company, limited liability company, partnership or other business entity, or any Governmental Authority.

1.23 " **Products** " means the beta units designated by GenMark in writing as saleable for commercial use and the production versions (including future versions thereof) of GenMark's integrated, fully-automated molecular diagnostics ePlex™ instrument system, comprising Bases, Bays, and Towers, to be manufactured and supplied by Plexus in accordance with this Agreement and the Manufacturing Documents.

1.24 " **Program Material** " shall mean the Technical Design History File (DHF) and Device Master Record (DMR) for the Products prepared and maintained in accordance with the Applicable Standards, the Manufacturing Instructions, and all other quality, compliance, manufacturing, engineering and technical documentation, instructions and information, product declarations, certifications, and reports (including design verification and test reports) related to the manufacture of the Products hereunder or that are sufficient or reasonably required to allow GenMark to manufacture the Products.

1.25 " **Quality Agreement** " means that certain Quality Assurance Agreement attached hereto as Exhibit A.

1.26 Reserved.

1.27 " **Safety Stock** " has the meaning set forth in Section 2.6 hereof.

1.28 " **Spare Parts** " means the spare parts for the Products to be identified and developed by the parties pursuant to Section 2.2 below, which shall be manufactured and/or supplied by Plexus pursuant to the terms of this Agreement.

1.29 " **Supply Failure** " means a failure by Plexus to supply Products or Spare Parts ordered pursuant to this Agreement on the Delivery Date or up to three (3) days prior to the Delivery Date for any reason other than Force Majeure (as defined in Section 11.6).

1.30 " **Specifications** " means GenMark's written specifications for the Products, manufacturing requirements, instructions, shipping,storage and labelling requirements, and quality control specifications and documentation, which are identified on Exhibit B or otherwise communicated by GenMark and accepted by Plexus in writing.

1.31 " **Testing Criteria** " means the quality control, inspection, release, and testing procedures to be performed by Plexus and related criteria to be achieved in testing for final Product release, the current version of which are set forth in the Specifications, as the same may be amended from time to time by mutual written agreement of the parties.

1.32 " **Tower** " means a tower which contains six (6) Bays and attaches to a Base, as more fully described in the Specifications.

ARTICLE II
PURCHASE OF PRODUCTS AND TERMS OF SALE

2.1 General . During the term of this Agreement, Plexus shall manufacture and sell to GenMark, and deliver to GenMark or its designees, the Products ordered by GenMark pursuant to the terms of this Agreement. Plexus shall not sell, transfer or deliver any Products to any party other than GenMark or its designee, except with GenMark's prior written consent. During the term of this Agreement and thereafter, GenMark shall have the exclusive right throughout the world to market, sell, place, lease or otherwise transfer Products to third parties and provide or have provided related repair and service support to its customers, including the provision of Spare Parts.

2.2 Spare Parts . Plexus shall supply Spare Parts for the Products as required by GenMark during the term of this Agreement. Not later than three (3) months following initial delivery of commercial Products, the parties will agree on the type and quantity of Spare Parts that are advisable to maintain in stock, and on a reasonable Spare Parts use and repair implementation plan, in each case to establish and maintain technical support of the Products for GenMark's customers, which the parties agree shall include certain field service and repair activities that may be performed by GenMark or its authorized third party representatives (" **GenMark Field Service** "). An initial Spare Parts list established by the parties and related prices therefor, as well as the GenMark Field Service mutually agreed by the parties, in each case as of the Effective Date, are set forth on Exhibit C hereto. The parties expect to further augment and/or modify the list of Spare Parts set forth on Exhibit C hereto and, in connection therewith, the parties shall negotiate in good faith to conclusion GenMark's related price for any additional Spare Parts not reflected on Exhibit C hereto as of the Effective Date, which shall not exceed the cost of such Material as set forth on the Bill of Materials plus *** for each such part and Spare Parts made by Plexus as per the applicable quote plus *** . Plexus shall only discontinue the supply of a Spare Part as a result of unavailability of such Spare Part from the manufacturer or because a better Spare Part becomes available, and in such event, Plexus shall provide GenMark with the opportunity to make final orders for any discontinued Spare Parts in accordance with Section 2.5.3.5 and shall cooperate with GenMark in connection with any warranty claims related to

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Spare Parts. Plexus shall pass through any and all warranties from the applicable manufacturers of Spare Parts to GenMark. If requested by either party during the term of this Agreement, the parties agree to develop a specific return and repair process for Spare Parts as an amendment to this Agreement.

2.3 Purchase Forecasts. Each month throughout the Term, GenMark shall provide Plexus with a non-binding, rolling forecast specifying the estimated quantity of Products and Spare Parts required by GenMark for the next 12 months on a monthly basis (the " **Supply Forecast** "). Plexus shall accept or reject the Supply Forecast in writing within *** of receipt of the Supply Forecast and in the event that no written rejection is received by GenMark within the said *** the Supply Forecast shall be treated as accepted by Plexus. In the event that the Supply Forecast is properly rejected, the parties shall work together in good faith to agree upon a Supply Forecast that is mutually acceptable within *** from Plexus' rejection.

2.4 Product Orders. Orders shall be placed by written purchase order at least *** prior to the requested Delivery Date and submitted by electronic mail or by other means agreed upon by the parties. Plexus shall accept or reject all orders within *** following receipt of same and shall deliver all orders that are accepted to the designated location on the date (a) committed to by Plexus in its order acknowledgment, and (b) which shall be no later than *** days following GenMark's requested delivery date pursuant to this Section 2.4 (unless a different date is mutually agreed by the parties with respect to volumes in excess of those reflected in Sections 2.5.1(a)-(c)) (the " **Delivery Date** "). GenMark shall have the right to cancel, without Plexus' recourse or incurring any costs, expenses or liabilities except for Materials as set forth in Section 2.5.3, any purchase order for which Plexus cannot propose a delivery date within *** days following the date any order is received, notwithstanding any action taken by Plexus under the applicable purchase order. It is understood that Plexus shall be required to accept orders that are for a quantity of Products and Spare Parts that are reflected in the *** of each Supply Forecast, and once accepted, such orders are binding and may not be changed by GenMark. If Plexus notifies GenMark of a problem or a potential Supply Failure, GenMark may direct expedited delivery and any increased costs due to expedited delivery shall be paid by and be the liability of Plexus. Any standard printed terms of purchase/sale provided by either party to the other in connection with such purchase and sale shall be disregarded, and the provisions of this Agreement shall govern such purchase and sale and shall supersede and control any additional, conflicting or inconsistent terms or conditions in any such forms.

2.5 Obligation to Supply.

2.5.1 General. Plexus shall accept and fill orders for Products and Spare Parts up to and including (a) *** of the quantities of Products and Spare Parts set forth in the *** of each Supply Forecast, (b) *** of the quantities of Products and Spare Parts set forth in the *** of each Supply Forecast, and (c) *** of the quantities of Products and Spare Parts set forth in the *** of each Supply Forecast. Plexus shall use all commercially reasonable efforts to accept and fill orders for Products and Spare Parts in excess thereof. GenMark acknowledges that repeated requests for upside Product orders beyond any Safety Stock agreed to by the parties may drain the supply chain unless the Forecast is updated in a reasonably timely manner. GenMark acknowledges and agrees that the ability to fulfill quantities in excess of the requirements set forth in this Section 2.5.1 may require Plexus to expedite Materials and GenMark agrees to pay such reasonable expediting fees. Plexus shall fill each purchase order for Products and Spare Parts in whole or in part by using the Safety Stock first (if and to the extent established in writing pursuant to Section 2.6). Any additional Products or Spare Parts required to complete GenMark's order shall be filled with newly manufactured Products and newly procured Spare Parts.

2.5.2 Alternative Manufacturing Location. Not later than three (3) months following initial delivery of commercial Products hereunder, the parties will work together to identify and develop an actionable plan with respect to a geographically remote Plexus facility as a second source of supply and manufacture for the Products and Spare Parts and to prepare a plan for implementation of production thereof at such second source of supply within a reasonable, agreed period of time (which shall take into account GenMark's supply needs). In connection with the establishment of such second source of supply, GenMark shall have the right to inspect and qualify such alternative second source and review planning of the new production facility processes and installations and process machinery that would be necessary in the event the plan or certain steps in the plan are executed. Plexus shall in good faith comply with such measures as reasonably requested by GenMark.

2.5.3 Materials. Unless otherwise agreed by GenMark, Plexus shall be responsible for obtaining and shall own and procure directly from the applicable vendors all Materials necessary for the manufacture of the Products. GenMark acknowledges that Plexus may be required by suppliers of Materials or it may be in the parties' mutual best interests for Plexus to procure Materials in minimum or economic order quantities ("MOQs") and those quantities may exceed GenMark's demand for Products as set forth in the Supply Forecasts. In addition, GenMark acknowledges that Plexus may be required by suppliers of Materials to procure the Materials at lead times greater than *** ("Long Lead Time Materials"). Plexus shall set forth MOQs for Materials on the Bill of Materials and GenMark's written acceptance of the Bill of Materials constitutes approval of MOQs. GenMark hereby authorizes Plexus to procure Materials necessary to meet the demand for Products set forth in the *** of the Supply Forecasts and GenMark's purchase orders, including Materials solely as necessary to support any increases in quantities

of Product in excess of the Supply Forecasts as set forth in Section 2.5.1(a)-(c) , plus directly associated MOQs and Long Lead Time Materials solely as necessary in support thereof, and agrees to be liable for such Materials in accordance with this Section 2.5.3 .

2.5.3.1 Material Inventory Reporting . On a quarterly basis or upon GenMark's request, Plexus will provide GenMark with an inventory report describing in detail the Materials maintained in inventory by Plexus (the " **Inventory Report** "). GenMark will respond to Plexus in writing within *** of receipt of the Inventory Report with any good faith disagreement to it, detailing with reasonable particularity the nature of any such disagreement. GenMark's failure to respond within such period will represent its acceptance of the Inventory Report. In the event GenMark disagrees with the Inventory Report, GenMark and Plexus will work in good faith to promptly resolve the disagreement, escalating such disagreement to executive management at the request of either party. Any undisputed portion of the Inventory Report shall be resolved pursuant to Sections 2.5.3.2 and 2.5.3.3 .

2.5.3.2 Aged Material Inventory Resolution . " **Aged Material** " means any Material procured by Plexus in accordance with Section 2.5.3 that remains in Plexus' inventory for *** or longer for reasons other than Plexus' failure to manufacture and deliver Products in accordance with GenMark's purchase orders issued in accordance with this Agreement and the Supply Forecast (and then only to the extent such Material is directly related to the failure to manufacture or deliver), unless such failure to manufacture and deliver is due solely to GenMark's request to delay timely delivery. For all Aged Materials, GenMark shall, upon Plexus' demand, elect one of the following options: (a) provide Plexus with a purchase order for Products that will consume such Aged Material within *** , (b) pay Plexus a cash deposit in the amount of the cost of such Material as set forth on the Bill of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost, such deposits to be reconciled quarterly, or (c) pay to Plexus a monthly inventory management fee in an amount equal to *** of the cost of such Material as set forth on the Bill of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. In addition, for Aged Materials held by Plexus for more than *** , GenMark shall purchase such Aged Materials from Plexus upon written demand at a price equal to the cost of such Material as set forth on the Bill of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. For purposes of this Agreement, the " **Applicable Materials Overhead Percentage** " shall equal the materials overhead percentage set forth in the current Product pricing for the applicable pricing tier based on the pricing tiers in effect as of the date of determination.

2.5.3.3 Obsolete Material Inventory Resolution . " **Obsolete Material** " means any Material procured by Plexus in accordance with Section 2.5.3 that is removed by GenMark from the Bill of Materials or remains on the Bill of Materials but has no demand for consumption of the Material within the next *** . For all Obsolete Materials, GenMark shall provide instructions to Plexus to either ship or scrap the Obsolete Materials and issue a purchase order for such Obsolete Materials to Plexus within *** after receiving written notice from Plexus, upon which Plexus shall invoice GenMark for the cost of such Material as set forth on the Bill of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. GenMark shall be responsible for any reasonable direct out-of-pocket costs or expenses associated with the scrapping of Materials under this Section 2.5.3.3 .

2.5.3.4 Material Inventory Mitigation . Plexus shall use all commercially reasonable efforts to minimize and mitigate Material liability for Aged Materials and Obsolete Materials, which shall include returning Materials to, or restocking Materials with, suppliers of Materials, canceling orders with suppliers of Materials, or using such Materials to satisfy the current demand of Plexus' other customers. GenMark agrees to assist Plexus in such efforts if appropriate and requested by Plexus. GenMark acknowledges that Plexus' mitigation efforts, even if successful, may result in cancellation, restocking, and similar charges imposed by suppliers of Materials. Plexus shall obtain GenMark's written approval prior to incurring such charges. If so approved by GenMark, GenMark shall pay Plexus for the charges imposed in accordance with Section 2.9 .

2.5.3.5 Material and Spare Part Last Time Buys . Plexus shall notify GenMark as soon as practicable after receiving notice from manufacturers that a Material or Spare Part is going end-of-life. At GenMark's request, Plexus shall coordinate a last time buy of end-of-life Materials or Spare Parts and hold such Materials or Spare Parts in Plexus' inventory for use in manufacturing Products or for Spare Part sales hereunder. Immediately upon receipt into Plexus' inventory, last time buy purchases of Materials or Spare Parts that are not covered by the *** of GenMark's most recent Supply Forecast shall be considered Aged Inventory and GenMark shall issue a cash deposit to Plexus or pay an inventory management fee in respect of such Material or Spare Parts to Plexus in accordance with Section 2.5.3.2 .

2.5.3.6 Material Invoicing . Invoices under this Section 2.5.3 shall be paid in accordance with Section 2.9 .

2.5.4 Vendor Arrangements . Plexus shall establish appropriate contracts with suppliers of raw or key Materials and shall exercise commercially reasonable efforts to ensure stability of, and long-term pricing for, Material supply.

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Plexus shall implement and, as necessary, update inventory management processes and procedures reasonably designed to ensure that Plexus has on hand, when necessary, sufficient Materials to manufacture, supply and deliver Products hereunder. Plexus shall use vendors for Materials used in the manufacture of the Products as directed or agreed to by GenMark, and shall not use any Materials or Material suppliers not approved by GenMark for the manufacture of the Products.

2.5.5 Supply Failure . Plexus shall communicate regularly with GenMark during the term of this Agreement regarding Plexus' ability to meet GenMark's Supply Forecast requirements and will promptly advise GenMark in writing of any anticipated Supply Failure event explaining the nature, impact and estimated duration of the Supply Failure event. Plexus shall use all commercially reasonable efforts to remedy the Supply Failure within a reasonable time at no additional cost to GenMark. If Plexus is unable to remedy the Supply Failure within *** after the start of the Supply Failure event, then Plexus shall consult with GenMark and the parties shall work together to remedy the Supply Failure, which the parties acknowledge may include formally commencing Product manufacturing activities at the alternative manufacturing location identified pursuant to Section 2.5.2 . Plexus hereby agrees to allow GenMark to provide such reasonable assistance to Plexus as the parties may deem necessary to avert or minimize any Supply Failure, including, without limitation, to sourcing or manufacturing with third parties' parts or raw materials that are in short supply; provided, however, that Plexus will not unreasonably refuse such offers of assistance by GenMark and GenMark will have no obligation or duty to offer such assistance. If Plexus is unable to remedy the Supply Failure, after an aggregate period of *** (or longer as agreed in writing by the parties), commencing with the date upon which such Supply Failure event began, then GenMark may at its option immediately terminate this Agreement upon written notice to Plexus.

2.6 Safety Stock . The Parties commit to diligently work together to develop the most appropriate supply chain model for the supply of Products and Spare Parts hereunder to support GenMark's Product supply and stocking needs. In the event safety stock of finished goods Products or of Materials held by Plexus is part of the agreed upon supply chain model, the consent to which shall not be unreasonably withheld by Plexus, the parties will agree to a quantity of safety stock to be held by Plexus and any associated costs in respect thereof prior to GenMark's first commercial sale of a Product (the "Safety Stock"). This Safety Stock shall remain separate and distinct from inventory held at the Facility and shall be stored by Plexus. Plexus will use Safety Stock to supply Products ordered by GenMark hereunder, and will maintain the appropriate level of Safety Stock by promptly replenishing that quantity of Products used in such supply. Plexus will manage Safety Stock on a "first in, first out" basis to fulfill GenMark's purchase orders on a routine basis. Plexus shall use all commercially reasonable efforts to replenish its Safety Stock within *** of use. GenMark shall purchase any Products remaining in Safety Stock for *** or longer upon written demand from Plexus. Plexus shall within *** of the end of the Replenishment Period notify GenMark in writing of its inability to replenish the Safety Stock as required herein.

2.7 Use of Subcontractors . Plexus shall not subcontract or otherwise use any third party for the performance of its obligations hereunder without GenMark's prior written consent. If GenMark consents to any subcontract or third party involvement hereunder, (a) the subcontractor or third party shall be required to enter into an agreement containing (i) confidentiality terms that are at least as restrictive as those in Article VII hereof and (ii) provisions for the assignment of inventions and intellectual property rights arising from the subcontracted work necessary and appropriate to effect the provisions of Article VI , and (b) Plexus shall supervise the work of any such subcontractor or other third party to ensure that the subcontractor's or other third party's work is in full compliance with all requirements of the Manufacturing Documents, the terms of this Agreement, and the Applicable Standards. Plexus shall remain responsible for any activities performed hereunder by any permitted subcontractor as if such activities were performed by Plexus.

2.8 Product Price .

2.8.1 Initial Pricing . The (a) price for beta versions of the Products, and (b) the pricing criteria which the parties shall use to establish initial production Product pricing at particular annual volumes of manufacture and Spare Parts (the "Pricing Criteria"), in each case is identified on Exhibit C . The initial prices for production Products shall be established and agreed to in writing by the parties in accordance with the Pricing Criteria prior to any purchase of production Products hereunder. Production Product pricing shall be reviewed regularly and adjusted as provided for herein.

2.8.2 *** Pricing Determination . Pricing for the Product Material line item only shall be re-quoted based on pricing tiers and mutually agreed *** ; provided that any and all other line items comprising Product pricing then in effect shall remain unchanged on a per-tier basis (which, to the extent such line items are calculated as a percentage of other Product pricing line items or a percentage of the aggregate Product cost, shall not exceed the percentages then in effect with respect to such tier). Prices applicable to individual purchase orders shall be initially determined based on the total quantity of Products forecast by GenMark on the Effective Date for Product purchases occurring between the Effective Date and December 31, 2015, and thereafter shall be based on GenMark's Product purchase estimates for *** during the term of this Agreement (each such *** forecast, *** " *** **Supply Forecast** "). GenMark shall provide the *** Supply Forecast to Plexus no later than *** of each *** during the term and Plexus shall respond with a pricing quotation for Products no later than *** after

receipt of the *** Supply Forecast.

2.8.3 *** Pricing Tier Review . No later than *** during the term, the Parties will conduct a *** pricing review and adjust pricing for the remainder of the calendar year if *** Volume calculated as of *** means a different price tier applies. " *** **Volume** " means the sum of (a) Product shipments occurring between *** and *** (which shall include any shipments not made during such period as a result of Force Majeure or Plexus' failure to fulfill Product orders submitted in accordance with this Agreement by the applicable Delivery Date), (b) the volume of Products in transit, if any, (c) the volume of Products in the current Forecast for the remainder of *** , and (d) the volume of Products in open purchase orders if such quantities are not reflected in such Forecast or are already in transit.

2.8.4 Pricing Adjustment Events . The parties shall review and agree to new pricing at the request of either party in the event the party making such request can reasonably demonstrate (a) changes to Products, Specifications, Testing Criteria, or additional GenMark requirements have directly impacted Product manufacturing or Material costs, or (b) market-driven Material cost fluctuations exceeding *** of the aggregate Materials cost line item of the current price have persisted for at least *** despite Plexus' commercially reasonable efforts to reduce or eliminate such price fluctuations (each, a " **Pricing Adjustment Event** "). Upon any such request by Plexus, Plexus shall promptly deliver to GenMark such documentation as reasonably requested by GenMark, consistent with past practice, to verify any purported cost increase related to the particular Pricing Adjustment Event. Within *** of such request and the parties' receipt of reasonably sufficient verification demonstrating an actual associated price increase has been incurred in respect of the particular Pricing Adjustment Event, the parties shall in good faith review the impact of such unforeseen circumstances and, if appropriate, agree on updated pricing solely to reflect the allocation of any agreed upon price increases resulting directly from the particular Pricing Adjustment Event, which shall be implemented on the date agreed by the parties. On the day any new pricing is implemented, Plexus will also write-down or write-up, as applicable, existing Materials on hand or on order held by Plexus to reflect the new agreed pricing and invoice or credit GenMark for such adjustment, as applicable. The parties agree to close any financial claims within *** of the effective date of any pricing adjustment implemented pursuant to this Section 2.8.4 .

2.8.5 Continuous Process Improvements . The parties acknowledge and agree that they will work together to identify, design and implement continuous Product and process improvements (" **CPIs** ") that aim to reduce Material costs and Plexus' own internal costs to achieve cost savings, which the parties agree shall include the detailed assessment of potential lower cost alternative manufacturing locations. Every *** during the term of this Agreement, Plexus shall prepare and deliver to GenMark a written report describing (a) proposed CPI projects and plans and related expected cost savings to be achieved upon implementation of such measures, and (b) the labor and Material cost savings (including labor cost reductions due to decreased labor for inspection and instrument manning requirements) achieved by Plexus due to the implementation of CPIs (" **CPI Cost Savings** "). CPI Cost Savings shall target at least a *** cost reduction each year over the pricing then in effect. Plexus shall in good faith consult with GenMark in establishing its CPI plans hereunder and shall implement all reasonable CPI Cost Savings opportunities reasonably requested by GenMark. The parties will agree on a process for reviewing CPI plans, the appropriate tool set for managing CPI initiatives as they are implemented, and any relevant communication plans or reporting, including an appropriate process for tracking, validating, and demonstrating the nature and amount of CPI Cost Savings. The benefit of any CPI Cost Savings shall (i) first, be immediately allocated to the party incurring the out-of-pocket expenses, if any, to implement the CPI Cost Savings, until such party is reimbursed for such expenses, (ii) second, provided that such CPI Cost Savings opportunity was first identified by Plexus, the parties shall thereafter immediately split such savings *** for *** after the reimbursement of expenses pursuant to subsection (i), and (iii) thereafter (or if GenMark first identifies such CPI Cost Savings opportunity), one hundred percent (100%) of the CPI Cost Savings shall be passed on to GenMark immediately.

2.8.6 Meetings . Representatives of both parties shall meet at least once each calendar quarter during the term of this Agreement and shall meet at such other times as deemed appropriate by either party. Representatives of each party attending such meetings must be appropriate for the tasks then being undertaken, in terms of their seniority, availability, and function in their respective organizations, training and experience. The purpose of such meetings is to serve as a venue for the parties to provide timely notice of their respective expectations for the next twelve (12) months, review CPI Costs Savings plans, execution, and realized savings (including in respect of Product manufacturing yield and its related impact on labor rates), as well as trends and developments they foresee in order to reduce the likelihood of surprises with respect to GenMark's demand for Products or Plexus' pricing for Products. Such representatives may meet in person or via teleconference, video conference or the like, provided that at least one (1) meeting every six (6) months shall be held in person. If meetings are held in person they shall be held at either the headquarters of Plexus or the headquarters of GenMark on an alternating basis, unless the parties mutually agree to hold such meeting in an alternative venue. Each party shall bear the expense of its respective representatives' participation in such meetings. The parties shall review and approve on a timely basis the expected forecasts for Products and the proposed pricing for Products for the next contract year. In the event that Plexus does not approve GenMark's expected forecast for Products or GenMark does not approve Plexus' proposed pricing for any Product(s) as presented at the meeting, then such party shall provide the other party with a detailed statement describing the basis of its concerns and the parties shall in good faith seek to resolve

such matter prior to the commencement of the next calendar year in accordance with the provisions of this Agreement.

2.9 Invoicing. Plexus shall submit invoices to GenMark for all shipments of Products hereunder upon shipment of such Products. The invoices shall reference GenMark's purchase order number and shall contain such other information as GenMark may reasonably request. GenMark shall pay any undisputed invoices for Products by electronic funds transfer within *** after the date of receipt of Plexus' invoice. All payments shall be stated and paid in United States Dollars. GenMark shall report any believed discrepancies in Plexus' invoices no later than *** after receipt of invoice. Undisputed invoices not paid within *** of their due date will be subject to an interest charge equal to the lesser of *** or the highest rate allowed by law.

2.10 Payment Disputes. In the event GenMark desires to dispute any item(s) under any invoice, GenMark will provide Plexus within *** after delivery of the invoice with written notice setting forth the details of the disputed item(s) and the amount in question. GenMark will timely pay to Plexus all undisputed amounts on any such invoice. The parties will work together, in good faith, to resolve such dispute within *** after such notice of dispute is sent. If the parties are unable to resolve a dispute within such *** period, the parties shall escalate such dispute for resolution pursuant to the provisions of Section 10.1 hereof. Despite any such escalation, Plexus shall not cease, postpone or terminate performance of its activities hereunder while such dispute is being resolved. GenMark's failure to pay the portion(s) of an invoice that it disputes in good faith using the procedure specified in this Section 2.10 shall not constitute a material breach under this Agreement.

2.11 Payment of Taxes. In addition to the prices quoted or invoiced, GenMark agrees to pay any taxes, duties or fees properly assessed on the Products, excluding any taxes on Plexus' income. In the event Plexus is required to pay such tax, duty or fee, GenMark shall reimburse Plexus within *** of written demand. If the transaction between Plexus and GenMark is exempt from all such taxes, duties and/or fees, GenMark shall provide Plexus with a tax exemption certificate or other document acceptable to the applicable authorities at the time the Purchase Order is placed.

2.12 Shipping. Products ordered by GenMark shall be shipped by Plexus FCA Plexus' manufacturing site for all shipments. Title to Products shall pass to GenMark when the Products are placed in the hands of the carrier at the shipping point.

2.13 Labelling. Plexus will supply Products to the locations designated by GenMark in finished and final packaged format for end user sale (including all trade dress, labeling and warning and handling instructions), as documented in the applicable Specifications for each Product. GenMark is solely responsible for specifying and validating finished device packaging and other packaging requirements, including any unique device identifier requirements, and for determining the content of any labeling, warning or handling instructions. Plexus shall label all Products in accordance with the Specifications and shall affix on each Product all regulatory compliance symbols that GenMark directs Plexus to affix on the Products or as otherwise set forth in the Specifications, including, but not limited to, the CE mark, and UL and/or CSA, RoHS and WEE symbols. GenMark is solely responsible for obtaining and maintaining the right to affix such regulatory compliance symbols on GenMark's Products. GenMark shall provide Plexus with Product labeling artwork or graphics as necessary for Plexus to comply with this Section 2.13.

2.14 Acceptance and Rejection.

2.14.1 General. Each Product shipment shall contain such quality control certificates as are necessary to demonstrate that the Product is in conformity with the Specifications and Testing Criteria, including a Certificate of Conformance (**"COC"**) in the form agreed to by the parties. GenMark shall notify Plexus within *** of delivery of a shipment of the Product of any apparent non-conformity of the Product to the Specifications. If GenMark fails to so notify Plexus, it will be deemed to have accepted the Product; *provided* that the warranties contained in Section 5.2 and Plexus' obligations under Section 8.1 shall survive acceptance of the Product by GenMark.

2.14.2 Release Testing. Plexus shall perform all in-process and finished Product tests or checks required by the Testing Criteria. For purposes of this Agreement, such tests are included in the price of the Products. All tests and test results shall be performed, documented and summarized by Plexus in accordance with the Testing Criteria and the Applicable Standards. Plexus shall immediately notify GenMark in writing of any significant out of specification testing results for either in process or finished Product test results.

2.14.3 Rejection. Plexus shall at its expense and at no further cost to GenMark repair or replace any Products that do not conform to the Specifications due to a failure of the Products to conform to the warranties provided by Plexus in Section 5.2. All defective units of the Product shall be returned to Plexus at Plexus' cost. In the event that GenMark notifies Plexus in writing of its rejection of Product under this Section 2.14, GenMark shall request a Return Material Authorization (**"RMA"**) number which shall be provided by Plexus as soon as reasonably practicable (but in any event within ***) and GenMark shall within *** of receipt of such RMA number return such rejected Product to Plexus at Plexus' expense. Plexus shall use all

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reasonable commercial endeavors to test the rejected Product promptly and in any event shall do so within *** of receipt of such rejected Product. In the event Plexus determines in good faith that the Product was properly rejected by GenMark, Plexus shall, at Plexus' election, repair or replace such defective Product within fifteen (15) business days of such determination or, *** . In the event that any rejected Product is determined by Plexus in good faith to not be properly rejected, and GenMark accepts such determination, such acceptance not to be unreasonably withheld, GenMark shall reimburse Plexus for all costs and expenses related to the return of such Product to GenMark. If there is disagreement between the parties as to whether any Product was properly rejected, the parties shall have such Product tested by a mutually agreed upon third party and such third party's determination as to whether such Product was properly rejected shall be binding on the parties. The expense for such testing shall be borne by Plexus unless it is determined that the Product in question was not properly rejected, in which case the expense shall be borne by GenMark.

2.14.3.1 Within Warranty Repair . Plexus will be responsible for (a) the shipping, delivery and insurance costs associated with the return and/or replacement of any Product which does not satisfy the warranties set forth in Section 5.2 of this Agreement (each, a " **Warranty Non-Compliant Product** "); (b) all costs and expenses incurred by or on behalf of Plexus or its Affiliates in connection with the repair, replacement or service of any Warranty Non-Compliant Product; *** .

2.14.3.2 No Fault Found Returns . Where a Product is returned to Plexus as being Warranty Non-Compliant but Plexus demonstrates (with supporting documents) to GenMark's reasonable satisfaction that the Product complies with the warranties set forth in Section 5.2 (each, a " **Warranty Compliant Product** "), then Plexus' investigation and Product (re)qualification costs will be charged to GenMark at Plexus quoted cost, which shall be reasonable and consistent with past practice, plus markup not to exceed *** , subject to generating and providing GenMark with a quotation for such costs, and the Product will be returned to GenMark, with GenMark covering return shipping, delivery and insurance costs.

2.14.4 Shortages . GenMark shall notify Plexus in writing of any shortage in quantity of any shipment of Product within *** of receipt of such Product. In the event of such shortage, Plexus shall use its reasonable efforts to make up and ship the shortage as promptly as possible, but with the substitute shipment occurring no later than *** after notice, at no additional cost to GenMark other than the price of the Products.

2.15 Intentionally Omitted.

2.16 Service and Repair . All service and repair activities (whether covered or not by the warranty given by Plexus pursuant to Section 5.2) requested of Plexus by GenMark will be performed by Plexus at the Facility (or such other location as approved in writing by GenMark) under an RMA number, and shall be completed promptly and without delay but in no event later than *** after Plexus receives the Product at issue, unless some other time period is set forth in a statement of work or proposal for service or repair activities. Serviced or repaired Products shall be warranted by Plexus until the date that is the later of: (a) the end of the original warranty period under Section 5.2 for the Product at issue; or (b) *** after the date the repaired Product is delivered by Plexus to GenMark. Plexus will send a quotation to GenMark and shall get GenMark's written consent to the quotation before starting any service or repair on any Warranty Compliant Product. With respect to any particular service or repair of a Warranty Compliant Product for which GenMark provides its written consent as provided above in this Section, Plexus will promptly proceed with such service or repair. GenMark will not be responsible for any such cost for service or repair of Warranty Non-Compliant Products. Plexus will provide a quality release document with each returned serviced and repaired Product. At GenMark's option and upon GenMark's request, Plexus will make available to GenMark, at GenMark's expense, the necessary documents, programs and Product-specific tools (or other tools to the extent not maintained by Plexus as trade secrets under applicable law) to allow GenMark to perform service and repair on Products at GenMark's premises and/or at customers' sites. Within sixty (60) days of the Effective Date, the parties agree to develop a comprehensive Product and Spare Parts service, repair and technical support program, which shall include GenMark Field Service as agreed by the parties in good faith.

ARTICLE III
REGULATORY AND QUALITY ARRANGEMENTS

3.1 Regulatory Approvals . GenMark shall perform and be responsible at its sole cost and expense for any clinical trials and regulatory activities that may be required to commercialize the Products (collectively , the " **Regulatory Approvals** "). GenMark shall have the exclusive right to determine in its sole discretion the strategy for Regulatory Approvals, including where and how to gain Regulatory Approvals. GenMark shall be the sole and exclusive owner of all right, title and interest in and to all Regulatory Approvals.

3.2 Cooperation . Plexus shall cooperate with GenMark in obtaining and maintaining such Regulatory Approvals as requested by GenMark, including through the furnishing of information required for Regulatory Approvals and submitting, if required, to regulatory audits and inspections by Governmental Authorities at the Facility. Plexus shall provide any Confidential Information that is required by a Governmental Authority in support of Regulatory Approvals and/or Product compliance either

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to GenMark or directly to the requesting Governmental Authority.

3.3 Regulatory Compliance . Plexus shall manufacture and produce Products hereunder, and maintain all necessary documentation and information in respect of such activities, including any Manufacturing Documents to be maintained by Plexus as agreed to by the parties, in each case in accordance with the Applicable Standards.

3.4 Rights of Monitoring, Inspection and Audit . Upon at least seven (7) days advanced notice and at a mutually agreeable time during normal business hours, GenMark shall have the right to have its representatives onsite at the Facility as part of its regular monitoring of the manufacturing activities to be conducted hereunder and/or to visit the Facility to conduct evaluations of Plexus' performance under this Agreement and its compliance herewith, in each case at GenMark's discretion. Plexus shall require that all approved agents or subcontractors hereunder shall grant GenMark reasonable access to their facilities and records to conduct evaluations of their performance under this Agreement and its compliance herewith. Plexus agrees to provide GenMark with access to such records and personnel as reasonably requested by GenMark for such purposes, including Plexus' quality control, testing, manufacturing, design records and other records and information reasonably related to the performance of its manufacture of the Products.

3.5 Regulatory Inspections . Plexus agrees to inform GenMark within twenty-four (24) hours of notification of any regulatory inquiry, communication or inspection, which reasonably relates to the manufacture of the Products or could impact Plexus's ability to manufacture or supply the Products. GenMark, at its option, shall have the right to have its representatives present at any such inspection by a Governmental Authority. In the event there are written observations (or any other written communication) by a Governmental Authority that involves any Product or could impact Plexus' ability to manufacture or supply any Product, or any proposed written response by Plexus to any such inspection or inquiry, Plexus will use reasonable efforts to provide GenMark with copies of all documentation prior to submission to the applicable Governmental Authority and shall have the opportunity to review and comment on the proposed response. If GenMark elects to provide input to the response, such input shall be provided by GenMark as promptly as possible and Plexus shall in good faith consider such input. Nothing herein shall limit GenMark's right to respond directly to any Governmental Authority if any questions are directed to GenMark.

3.6 Incidents or Accidents . Plexus shall immediately notify GenMark in writing of any incident or accident experienced by Plexus that may affect the quality of the Products or its ability to timely perform its obligations hereunder. Such incident or accident shall be immediately investigated by Plexus, and Plexus shall provide a written report within *** business days of the results of the investigation of such incidence or accident to GenMark.

3.7 Quality Assurance . The parties shall comply with the terms of the Quality Agreement in the performance of their activities hereunder. Prior to shipping any Product, Plexus will carry out the Product tests specified in the Testing Criteria. If any Product fails to meet such requirements, such non-conformance shall be handled in accordance with the Manufacturing Documents or as otherwise directed by GenMark. No Product will be shipped to GenMark or its designee without passing all tests specified in the Manufacturing Documents, except with GenMark's prior written approval. Plexus will maintain manufacturing quality documentation, including records of its Product tests, in accordance with the Applicable Standards.

3.8 Product Changes . Plexus shall not make any change to any Product's design, manufacturing process, Materials, Material suppliers or components without GenMark's prior written approval. If any such changes to the Products are authorized in writing by GenMark, such changes must comply with the terms of the Quality Agreement. Upon GenMark's request, Plexus agrees that it will facilitate all changes to the Specifications that are necessary or appropriate under applicable laws, as determined by GenMark, or GenMark's performance requirements and GenMark shall update the Specifications accordingly and communicate the changes in writing to Plexus. Plexus shall exercise all commercially reasonable efforts to implement any changes to the Products approved by GenMark hereunder as soon as reasonably practicable, but in any event within *** from the date of GenMark's written approval thereof. " **Engineering Change** " means modifications to the Specifications by GenMark that (1) affect the form, fit, function, delivery schedule, performance, reliability, appearance, dimensions, tolerance, safety or purchase price of such Products or (2) require additional or modified Testing Criteria. GenMark agrees to submit all Engineering Changes to Plexus in writing. Plexus will use commercially reasonable efforts to respond to GenMark within *** with a written evaluation of the Engineering Change including: (a) the administrative cost to implement the Engineering Change; (b) the cost to modify GenMark Equipment or related non-recurring expenses; (c) the quantity of Materials that will become Obsolete Materials due to the Engineering Change; (d) the cost to rework work-in-progress Products; (e) any Product price adjustment resulting from the Engineering Change; (f) the expected effect on the delivery schedule; and (g) the manner in which the Engineering Change will be implemented.

3.9 Reserved.

3.10 Change Control . Plexus shall establish and maintain an effective and compliant Change Control for changes to

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the design of the Products in accordance with the Manufacturing Documents and GenMark's instructions.

3.11 Vigilance . Plexus shall promptly notify GenMark if it becomes aware of any information about the Products indicating that it may not conform to the Specifications or otherwise perform as intended. The parties will promptly confer to discuss such circumstances and to consider appropriate courses of action. In the event that (a) an event, incident, or circumstance may result in the need for a removal of any Product or any lot or lots thereof from the market or any regulatory reportable event occurs which is attributable to the Product, (b) any Governmental Authority threatens to prohibit the use of any Product as a result of a defect of the Product, or (c) any Governmental Authority requires distribution of a "Dear Doctor" letter or its equivalent regarding the use of any Product, in each case the parties shall promptly advise each other in writing, and shall provide each other with copies of all relevant correspondence, notices and the like. Notwithstanding anything to the contrary herein, GenMark shall have final authority to make all decisions relating to corrective and/or preventive action with respect to Products. Internal investigation of any such event will take place promptly after the parties become aware of the reportable event and the root cause and appropriate remedial measures will be determined and documented to the best of the parties' capabilities. GenMark or its designee will make all contacts with any Governmental Authorities in respect of any event described in this Section 3.11 and will be responsible for coordinating all of the necessary activities in connection with such action. Plexus will cooperate with GenMark in the conduct of any such activities. Notwithstanding anything to the contrary herein, GenMark is solely responsible for all complaint handling, including, without limitation, maintenance of complaint files, investigation and resolution of complaints, trend analysis of complaints, and maintenance of complaint-related records. GenMark is solely responsible for FDA medical device reporting obligations under 21 CFR Part 803 and similar reporting regulations in jurisdictions outside the United States. GenMark shall promptly provide to Plexus copies of all written complaints of any Governmental Authority received by GenMark that relate to any Product. Plexus shall provide to GenMark information regarding any complaints Plexus receives about the Products.

3.12 Reliability Requirements . During the term hereof, the parties agree to cooperate in good faith with each other and provide such data and information, including service and reliability data, statistics and analyses relating to failure rates, failure mechanisms and repair times to one another on a quarterly basis or as otherwise reasonably requested by either party as necessary or appropriate to determine whether and to what extent the Products satisfy GenMark's reasonable reliability requirements (which shall be consistent with industry standards). All such information shall be subject to the confidentiality provisions of Article VII hereof. If one or more Product(s) fails to achieve such reliability requirements during the term hereof, the parties agree to mutually perform an analysis to determine the root cause(s) for such failure(s).

3.13 Program Material . Within *** of a written request received from GenMark, Plexus shall provide GenMark with complete and current copies of all Program Material requested by GenMark.

3.14 Decontamination Prior to Return of Products . GenMark shall ensure that all Products are decontaminated in accordance with a mutually agreed-upon decontamination process prior to shipment to Plexus for repair or other services and that all appropriate documentation and/or certification of such decontamination accompanies the Products.

3.15 Material Traceability . GenMark is responsible for identifying critical Materials that require component level traceability. GenMark shall select the appropriate component level or device level traceability grade, in order to meet any applicable regulations or requirements of Governmental Authorities.

3.16 Software Validation . GenMark is responsible for the validation of any software embedded in the Products and the validation of all GenMark-supplied: (1) test equipment or software; (2) production equipment or software; and (3) firmware. Plexus is responsible for the validation of any Plexus software used in production or as part of the Plexus quality system.

ARTICLE IV
EQUIPMENT

4.1 GenMark Equipment . GenMark and Plexus shall maintain accurate books and records of all GenMark Equipment. A preliminary list of the GenMark Equipment is set forth on Exhibit D hereto. The parties shall maintain an updated list of GenMark Equipment to be used at the Facility throughout the term of the Agreement. GenMark shall at all times hold exclusive title to the GenMark Equipment and may assign, transfer, pledge or sell its interest in the GenMark Equipment without notice to or approval from Plexus. Plexus shall exercise due care and hold, store and protect the GenMark Equipment at the Facility as a bailee during the term of this Agreement, subject to the terms and conditions contained herein. All GenMark Equipment shall be physically segregated at the Facility from all other inventory, products, material, equipment or other personal property of Plexus or any third party and shall be clearly labeled at the Facility and within Plexus' books and records as the " **Property of GenMark Diagnostics, Inc.** " Plexus shall not use the GenMark Equipment for its own benefit or for the benefit of any third party, nor shall Plexus use the GenMark Equipment for any other purpose other than manufacturing Products hereunder. GenMark shall have the right at any time to inspect the GenMark Equipment to ensure Plexus' compliance hereunder. In the event Plexus procures equipment

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on GenMark's behalf, title to the equipment shall pass to GenMark when Plexus receives payment in full for the equipment, at which time, such equipment shall become GenMark Equipment. Plexus shall provide general/routine maintenance of GenMark Equipment at no charge during the term of this Agreement. Upon GenMark's request or per GenMark Equipment maintenance instructions, Plexus shall provide specific maintenance, repair, calibration, or upgrade services at GenMark's expense on a time and materials basis. Plexus shall notify GenMark in advance and obtain the written agreement of GenMark with respect to any such specific maintenance, repair or calibration prior to taking such action. Replacement parts for GenMark Equipment will be charged at Plexus's cost plus quoted markup not to exceed *** .

4.2 Protection of GenMark Equipment . Plexus shall not make available or purport to sell, lease or convey to any third party or permit any third party to assert or attach any liens on or against the GenMark Equipment, nor shall Plexus, by agreement or otherwise, use the GenMark Equipment as collateral in any secured transaction or perfect any security interest in the same or otherwise encumber the GenMark Equipment. Plexus shall execute such other instruments and other assurances as GenMark may request in order to confirm and protect GenMark's exclusive ownership of the GenMark Equipment. Plexus agrees that if any third party attempts to claim ownership of the GenMark Equipment by asserting a claim against Plexus or through Plexus, Plexus will take all actions necessary or useful to permit GenMark to protect its title to the GenMark Equipment, including, without limitation, executing any documents or powers-of-attorney as reasonably necessary to accomplish the same.

4.3 Unconditional Right to Remove GenMark Equipment . GenMark shall have the unconditional right to remove and reclaim the GenMark Equipment from the Facility at any time and for any reason whatsoever upon written notice to Plexus, and Plexus shall provide all assistance necessary or useful to permit GenMark to remove the GenMark Equipment from the Facility. If GenMark's request for the return of GenMark Equipment materially adversely impacts Plexus's ability to perform its obligations under this Agreement, Plexus shall be relieved from all obligations under this Agreement which require access to and use of such GenMark Equipment.

ARTICLE V
REPRESENTATIONS AND WARRANTIES

5.1 Mutual Representations and Warranties . Each of GenMark and Plexus hereby represents and warrants as of the Effective Date (except as specifically otherwise indicated below) as follows:

5.1.1 Corporate Existence and Power . Such party: (a) is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated; (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (c) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such party and would not materially adversely affect such party's ability to perform its obligations under this Agreement.

5.1.2 Authorization and Enforcement of Obligations . Such party: (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid and binding obligation, enforceable against such party in accordance with its terms.

5.1.3 Consents . All necessary consents, approvals and authorizations of all Persons required to be obtained by such party in connection with the execution of this Agreement have been obtained on or before the Effective Date.

5.1.4 No Conflict . The execution and delivery of this Agreement and the performance of such party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any material contractual obligation of such party.

5.2 Plexus' Manufacturing Warranties .

5.2.1 General . Plexus warrants to GenMark that for a warranty period of *** after the date of delivery (a) all Products shall be manufactured, processed, labeled, packaged, stored and tested in accordance with the Manufacturing Documents, and the terms of this Agreement, (b) that all Products supplied hereunder shall be manufactured in conformance with the Specifications, (c) that it will convey good title to each Product shipped under this Agreement, (d) each Product will be delivered free from any security interest, lien or encumbrance, and (e) the Products shall be free of any defects in workmanship. Plexus shall exercise its *** to obtain warranty rights from suppliers of Material consistent with the warranties provided by Plexus herein, and pass through or assign to GenMark such warranty rights, to the extent that such rights are able to be passed through or assigned.

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In the event of a non-conformance in Materials, Plexus shall coordinate with and be the point of contact for resolution of the problem through the applicable supplier and, upon becoming aware of the problem, will notify the supplier and will use all reasonable efforts to cause the supplier to promptly repair or replace the nonconforming Material in accordance with the supplier's warranty. Provided the defective Material should have been detected by following the Testing Criteria (but such defective Material was not detected due to Plexus improperly executing the Testing Criteria prior to release to GenMark), any rework or service to repair a Product due to a Material defect within fifteen (15) months of GenMark's purchase hereunder shall be performed by Plexus and GenMark shall pay *** of Plexus' *** (not including the actual cost to replace the defective Materials, which will be fully borne by GenMark unless otherwise covered by such Material supplier's warranty) to perform such rework and repair such Product to become a Warranty Compliant Product.

5.2.2 Remedy . In the event any Product fails to conform to the warranties set forth in Section 5.2.1 , Plexus shall, at Plexus' election, repair or replace the Products *** . GenMark shall request a Return Materials Authorization (RMA) number from Plexus and return any Products not conforming to the warranties set forth in Section 5.2.1 bearing such RMA number. Plexus' warranty for replaced or repaired Products shall be the longer of (1) the duration of the warranty remaining on the original Product returned under warranty, or (2) *** from the date of shipment of the replaced or repaired Product.

5.2.3 Limitations . The warranties provided in Section 5.2 do not apply to (1) malfunctions, defects, or failures resulting from (a) misuse, (b) abuse, (c) accident, (d) neglect, (e) improper installation, operation, maintenance or repairs, (f) acts of God, (g) power failures or surges or (h) alterations, modifications, or repairs (" **Repairs** ") by any party other than Plexus, except for GenMark Field Service, provided GenMark Field Service does not make any Repairs outside the scope of Repairs the Parties agree in writing are acceptable for GenMark Field Service to perform; (2) any defect not made known by GenMark during the warranty period; and (3) Products shipped by Plexus and not tested according to the Testing Criteria at the direction of GenMark

5.2.4 Disclaimer. THE REMEDIES PROVIDED IN THIS SECTION 5.2 CONSTITUTE GENMARK'S SOLE AND EXCLUSIVE REMEDIES AGAINST PLEXUS FOR BREACH OF WARRANTY CLAIMS. EXCEPT AS PROVIDED IN SECTIONS 5.1 AND 5.2 , PLEXUS MAKES NO WARRANTIES OF ANY KIND WITH RESPECT TO THE PRODUCTS OR ITS SERVICES HEREUNDER, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES RESPECTING NONINFRINGEMENT, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY IMPLIED WARRANTIES ARISING FROM A COURSE OF PERFORMANCE, A COURSE OF DEALING, OR TRADE USAGE.

ARTICLE VI
PROPRIETARY RIGHTS

6.1 Definitions . " **Plexus Background IP** " means Intellectual Property Rights (i) existing as of the Effective Date, (ii) developed independently from this Agreement, or (iii) developed without the use of GenMark's Confidential Information.

6.2 Product Intellectual Property . Plexus hereby acknowledges and agrees that, except for Plexus Background IP, as between the parties, any and all Intellectual Property Rights necessary for or otherwise embodied in the Products and its design are and shall be and remain solely and exclusively owned by GenMark. The parties agree that the *** .

6.3 Limited License to GenMark Intellectual Property Rights . During the term of this Agreement, GenMark grants Plexus a non-exclusive, non-transferable, limited right and license, without right to sublicense, to the GenMark Intellectual Property Rights solely to the extent necessary to manufacture and test Products for GenMark pursuant to the terms of this Agreement. No other rights, expressed or implied, to the GenMark Intellectual Property Rights are granted to Plexus hereunder.

6.4 Manufacturing Instructions . Except as set forth in this Section 6.4 , all right, title and interest to the Manufacturing Instructions shall be *** . Plexus hereby grants to GenMark a *** license to use the *** as necessary or helpful to manufacture or have manufactured the Products or any other products of GenMark or its Affiliates. In addition, the parties acknowledge and agree that Plexus will ensure that the Manufacturing Instructions are set forth in writing and will promptly, and in any event with *** , provide a complete set of the same to GenMark from time to time upon GenMark's request. All rights and licenses granted to GenMark under or pursuant to this Section 6.4 are, and shall otherwise be deemed to be, for purposes of Paragraph 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Paragraph 101(35A) of the U.S. Bankruptcy Code. The parties agree that GenMark, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code.

6.5 Inventions . GenMark shall solely and exclusively own the right to any and all Intellectual Property Rights that are conceived or reduced to practice by Plexus in its performance of this Agreement, except for Plexus Background IP

("Inventions"). Plexus hereby irrevocably assigns and conveys to GenMark all right, title and interest worldwide in and to any and all Inventions as described in this Section 6.5 and agrees to execute any and all legal instruments and provide such other cooperation to GenMark as reasonably requested by GenMark, at GenMark's expense, to effect, acknowledge or perfect such assignment and conveyance and maintain and prosecute such rights. Plexus represents and warrants that it has entered into or will enter into written agreements with all employees or other approved agents or representatives of Plexus performing activities hereunder necessary and appropriate to perfect GenMark's ownership in all Inventions. Plexus retains no rights to use any Inventions and agrees not to challenge the validity of GenMark's ownership of the Inventions. Plexus shall make a complete and prompt written disclosure to GenMark specifically detailing the features and concepts of any and all Inventions that are conceived or reduced to practice by Plexus and/or persons working under its direction in the manufacture of Products under this Agreement.

6.6 Enforcement . GenMark shall have the sole power, authority and discretion to enforce and exploit the GenMark Intellectual Property Rights and Inventions against third parties. Plexus shall cooperate and assist GenMark as requested by GenMark in any legal action to enforce such rights. All costs of any such legal action, including any costs and expenses actually incurred by Plexus to support GenMark's requests for assistance, shall be borne by GenMark, and any monetary relief granted as a result of such legal action shall accrue solely to GenMark. Plexus agrees to provide GenMark with prompt notice to the extent it has actual knowledge of, or reasonably suspects, any third party usage or infringement of the GenMark Intellectual Property Rights or Inventions.

ARTICLE VII
CONFIDENTIALITY

7.1 Confidentiality Obligations . During the term of this Agreement and thereafter, each party: (a) shall treat as confidential all Confidential Information provided to the receiving party by the disclosing party, (b) shall not use such Confidential Information except as expressly permitted under the terms of this Agreement or otherwise authorized in writing by the disclosing party, (c) shall implement reasonable procedures to prohibit the disclosure, unauthorized duplication, misuse or removal of such Confidential Information, and (d) shall not disclose such Confidential Information to any third party unless it is necessary to fulfill one or more obligations expressly required by this Agreement, and provided that such third party agrees in writing to be bound by terms of confidentiality at least equivalent to those set forth in this Article VII . Without limiting the foregoing, each of the parties shall use at least the same procedures and degree of care to prevent the disclosure of Confidential Information as its uses to prevent the disclosure of its own confidential information of like importance, and shall in any event use no less than reasonable procedures and a reasonable degree of care. For purposes of this Article VII , " **Confidential Information** " means any and all non-public and proprietary information that is designated as such and that is disclosed by either party to the other (including, without limitation, the GenMark Intellectual Property Rights and Plexus Background IP) in any form in connection with this Agreement and that, if orally disclosed, shall be identified in writing within thirty (30) days of such disclosure. A receiving party shall notify the disclosing party promptly upon discovery of any unauthorized use or disclosure of the disclosing party's Confidential Information. Upon the expiration or earlier termination of this Agreement, each party shall return to the other party all tangible items regarding the Confidential Information of the other party and all copies thereof; *provided, however* , that a receiving party shall have the right to retain one (1) copy for its legal files for the sole purpose of determining its obligations hereunder.

7.2 Permitted Disclosure . The obligations set forth in Section 7.1 shall not apply to any information to the extent it can be established by the receiving party that such information:

(a) was generally known and available to the public at the time it was disclosed, or becomes generally known and available to the public through no fault of the receiving party;
(b) was known to the receiving party at the time of disclosure as shown by written records in existence at the time of disclosure, or was independently developed by the receiving party or its Affiliates without the benefit of Confidential Information;
(c) is disclosed with the prior written approval of the disclosing party;
(d) becomes known to the receiving party from a third party without breach of this Agreement by the receiving party and in a manner that is otherwise not in violation of the disclosing party's rights; or
(e) is disclosed by the receiving party pursuant to the order or requirement of a court, administrative agency or other governmental body; provided, however, that the receiving party shall provide reasonable advance notice to enable the disclosing party, with the cooperation of the receiving party, to seek a protective order, confidential treatment order, or otherwise prevent or restrict such disclosure.

7.3 Agreement and Terms Confidential . Unless otherwise agreed to in writing or as necessary to comply with a valid legal order of a court of law or agency of competent jurisdiction, both the existence and terms of this Agreement shall be deemed Confidential Information. If either party is required by the United States Securities and Exchange Commission (or

other similar Governmental Authority) to disclose this Agreement or any of its terms, such party shall consult with the other party, and give due consideration to such party's comments regarding which terms the disclosing party may make the subject of a confidential treatment request. For the period commencing on the Effective Date and ending on the expiration or earlier termination hereof, without the prior express written consent of the other party, neither party shall originate any initial disclosure to any third party of the existence or terms of this Agreement (unless pursuant to an appropriate confidentiality agreement), or originate any initial publicity, news release or any other public announcement (written or oral) relating to this Agreement, the existence of an arrangement between the parties, or otherwise utilizing the other party's trademarks or trade names.

ARTICLE VIII
INDEMNIFICATION AND INSURANCE

8.1 Indemnification Obligations .

8.1.1 Indemnification by Plexus . Plexus shall defend, indemnify and hold harmless GenMark and its Affiliates and their respective officers, directors, employees and agents (the " **GenMark Indemnified Parties** ") from and against any and all claims, suits or other actions made by a third party (collectively, " **Claims** ") and all related losses, expenses, damages, costs and liabilities (including reasonable attorneys' fees) (collectively, " **Losses** "), arising out of or attributable to (a) the negligence or willful misconduct of Plexus, its Affiliates, or their respective officers, directors or employees in connection with the performance of their obligations under this Agreement resulting in bodily injury, death, or damage to tangible property; or (b) *** *provided, however* , that the foregoing obligation shall not apply to the extent such Losses are Losses for which GenMark must indemnify Plexus under Section 8.1.2 .

8.1.2 Indemnification by GenMark . GenMark shall defend, indemnify and hold harmless Plexus and its Affiliates and their respective officers, directors, employees and agents (the " **Plexus Indemnified Parties** ") from and against any and all Claims and all related Losses, arising out of or attributable to (a) Plexus' manufacture of the aspect(s) of the Products in accordance with the Specifications which give rise to such Claim, (b) the negligence or willful misconduct of GenMark, its Affiliates, or their respective officers, directors or employees in connection with the performance of their obligations under this Agreement resulting in bodily injury, death, or damage to tangible property, (c) the marketing, distribution and sale of Products, or (d) infringement or misappropriation by the Products of any third-party Intellectual Property Right; *provided, however* , that the foregoing obligation shall not apply to the extent that such Losses are Losses for which Plexus must indemnify GenMark under Section 8.1.1 .

8.1.3 Indemnification Procedures . The parties shall promptly notify each other of any claims or suits with respect to which indemnification is sought hereunder. The party requesting indemnification shall permit the indemnifying party to assume the defense at the indemnifying party's sole expense, of such claims or suits giving rise to indemnification hereunder. The indemnified party shall provide reasonable cooperation to the indemnifying party at the indemnifying party's expense. The indemnified party may participate in any such proceedings with counsel of its own choosing at the indemnified party's expense. No settlement or compromise shall be binding on a party to this Agreement without such party's prior written consent, which consent shall not be unreasonably withheld.

8.2 Limitation of Liability . neither party shall be liable TO THE OTHER for LOST PROFITS OR FOR ANY indirect, incidental, consequential, special, PUNITIVE or exemplary damages IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, however caused, under any theory of liability INCLUDING CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND NOTWITHSTANDING THAT SUCH DAMAGES MAY HAVE BEEN IN THE REASONABLE CONTEMPLATION OF THE PARTIES. the limitations of liability set forth in this section 8.2 shall not apply to BREACH OF CONFIDENTIALITY OBLIGATIONS OR VIOLATIONS OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS HEREUNDER, OR TO A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

8.3 Insurance . Each party shall, at its own expense, procure and maintain insurance with a financially sound insurance company having an A.M. Best Rating of AX or better in the areas of worker's compensation; employer's liability for bodily injury suffered through accident or disease; commercial general liability; and product liability with limits of no less than *** per occurrence for bodily injury and *** per occurrence for property damage and with limits for comprehensive general liability and product liability that are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being commercially distributed or sold by GenMark. Upon written request, a party shall furnish the other party with a certificate of insurance evidencing the coverage required hereunder and shall provide thirty (30) days' prior written notice to the other party in the event of cancellation or material adverse change in such coverage. It is understood that

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such insurance shall not be construed to create a limit of either party's liability with respect to its indemnification obligations under Section 8.1.

ARTICLE IX
TERM AND TERMINATION

9.1 Term and Termination. The term of this Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to this Section 9.1, shall continue until the fifth (5th) anniversary of the Effective Date, after which it shall renew automatically for successive two (2) year periods unless either party provides the other party with written notice at least twelve (12) months in advance of a scheduled renewal date of its intent not to renew this Agreement.

9.1.1 Termination for Insolvency. Either party may terminate this Agreement upon thirty (30) days prior written notice to the other party if the other party has experienced an Insolvency Event.

9.1.2 Termination for Breach. Either party may terminate this Agreement after the material breach of this Agreement by the other party, unless the breaching party has cured a non-payment breach within *** days after written notice thereof from the non-breaching party or a payment breach within *** days after written notice thereof from the non-breaching party.

9.1.3 Termination for Convenience. Either party shall have the right to terminate this Agreement for its convenience, with or without cause, at any time after *** of the Effective Date upon *** written notice to the other party. In the event Plexus exercises its right to terminate for convenience pursuant to this Section 9.1.3 during the initial five (5) years of the term, Plexus shall (a) cooperate with GenMark in effecting the disclosure and transfer of all *** , Product-specific know-how and Product-specific quality control procedures as are necessary or useful to commence and continue the uninterrupted manufacture and supply of Products and Spare Parts, (b) continue the uninterrupted supply of Products and Spare Parts pursuant to the terms of this Agreement until GenMark's alternative supply source has been validated but in no event longer than *** after the expiration of the *** notice period, (c) cover the reasonable costs and expenses associated with shipping test fixtures and Materials to GenMark or its designee, and (d) at GenMark's request, Plexus shall coordinate a last-time-buy of Materials and/or Spare Parts.

9.2 Effect of Termination.

9.2.1 Survival. Notwithstanding anything contained in this Agreement to the contrary, termination of this Agreement shall not relieve the parties of their respective obligations or liability to the other accrued hereunder prior to the effective date of termination. The following provisions shall survive the termination or expiration of this Agreement: Section 2.2 (Spare Parts); Section 4.3 (Unconditional Right to Remove GenMark Equipment); Section 5.2 (Plexus' Manufacturing Warranties); Article VI (Proprietary Rights); Article VII (Confidentiality); Section 8.1 (Indemnification Obligations); Section 8.2 (Limitation of Liability); Section 9.2 (Effect of Termination); Section 9.3 (Return of Information and Cooperation); Article X (Arbitration); Section 11.1 (Interpretation); Section 11.3 (Notices); Section 11.8 (Governing Law); Section 11.9 (Legal Counsel); Section 11.11 (Severability); Section 11.12 (Headings); and any other provisions of this Agreement which by their nature or context are intended or required to survive the expiration or termination of this Agreement.

9.2.2 Non-Exclusive Remedy. Termination of this Agreement shall be in addition to, and shall not prejudice, the parties' remedies at law or in equity, including, without limitation, the parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

9.2.3 Return of Information and Cooperation. In the event of termination of this Agreement, Plexus shall promptly return and provide to GenMark all Program Material and Confidential Information of GenMark. Upon any termination (including expiration) of this Agreement, the parties will cooperate to minimize disruption to GenMark's customers and to provide for the continued manufacture of Products if so requested by GenMark. Except in the event of termination arising from GenMark's breach of this Agreement, Plexus will fill existing orders that Plexus has received and accepted.

9.2.4 Inventory. Upon termination of this Agreement for any reason, all outstanding purchase orders may, at GenMark's written election, be canceled. Otherwise, Plexus will perform under such purchase orders and the provisions of this Agreement will survive termination and apply to such performance. If this Agreement is terminated by GenMark pursuant to Section 9.1.3 or by Plexus pursuant to Section 9.1.2, GenMark agrees to pay Plexus for (1) any finished goods Products; (2) any work-in-progress Products; and (3) provided that Plexus procured the Materials in accordance with this Agreement, any Materials, at the cost set forth on the Bill of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost, on hand, on order or for which Plexus is obligated to purchase as of the date of termination, subject to Plexus' obligation

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to mitigate and limit all such amounts in accordance with Section 2.5.3.4 . In the event this Agreement is terminated by GenMark pursuant to Section 9.1.2 , GenMark agrees to pay Plexus for (1) any finished goods Products; and (2) provided that Plexus procured the Materials in accordance with this Agreement, any Materials, at cost set forth on the Bill of Materials, on hand, or on order or for which Plexus is obligated to purchase as of the date of termination, subject to Plexus' obligation to mitigate and limit all such amounts in accordance with Section 2.5.3.4 .

ARTICLE X
ARBITRATION

10.1 Disputes . Except as otherwise expressly provided in this Agreement, any controversy, claim or legal proceeding arising out of or relating to this Agreement, or the breach, termination or invalidity thereof (" **Dispute** ") shall be first referred to GenMark's Chief Executive Officer and Plexus' Chief Customer Officer for resolution, prior to proceeding under the other provisions of this Article X . A Dispute shall be referred to such executives upon one party providing the other party with notice that such Dispute exists, and such executives (or their designees) shall attempt to resolve such Dispute through good faith discussions. In the event that such Dispute is not resolved within thirty (30) days of such other party's receipt of such notice, subject to Section 10.3 , either party may initiate the Dispute resolution provisions in Section 10.2 . The parties agree that any discussions between such executives (or their designees) regarding such Dispute do not constitute settlement discussions, unless the parties agree otherwise in writing.

10.2 Arbitration . Subject to Sections 10.1 and 10.3 , the parties agree to resolve any Dispute exclusively through binding arbitration conducted under the auspices of the American Arbitration Association (the " **AAA** ") pursuant to AAA's Commercial Arbitration Rules presently in effect. The parties shall appoint an arbitrator with at least ten (10) years of experience as an attorney and experience in the medical diagnostics industry so as to better understand the legal, business and scientific issues addressed in the arbitration. Any arbitration hereunder shall be brought in San Diego, California. Unless agreed otherwise by the parties, the parties shall have thirty (30) days from the appointment of the arbitrator to present and/or submit their positions to the arbitrator, and the parties shall have a hearing before the arbitrator within ten (10) business days of such submission. Each party agrees to use reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrator may deem any party as "necessary." The arbitrator shall hear evidence by each party and resolve each of the issues identified by the parties. The arbitrator shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue which clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the parties as expeditiously as possible, but in no event more than thirty (30) days after conclusion of the hearing, unless otherwise agreed to by the parties. The parties shall use all reasonable efforts to keep arbitration costs to a minimum. Each party must bear its own attorneys' fees and associated costs and expenses. Each party agrees that, notwithstanding any provision of applicable law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against any party.

10.3 Subject Matter Exclusions . Notwithstanding the foregoing, the provisions of Sections 10.1 and 10.2 shall not apply to any Dispute relating to: (a) the validity, infringement, enforceability or claim interpretation relating to a party's patents, trademarks or copyrights, which, for patents that are issued in the United States, shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants reside; or (b) any antitrust, antimonopoly or competition law or regulation, whether or not statutory.

10.4 Equitable Relief . Nothing in this Agreement shall be deemed as preventing the parties from seeking injunctive relief (or other provisional remedy) from any court having jurisdiction over the parties and the subject matter of the dispute as necessary to protect either party's interests.

ARTICLE XI
MISCELLANEOUS PROVISIONS

11.1 Interpretation . In this Agreement, unless a clear contrary intention appears:

(a) the singular number includes the plural number and *vice versa* ;

(b) reference to any person or entity includes such person's or entity's successors and assigns;

(c) reference to any law, rule, regulation, order, decree, requirement, policy, guideline, directive or interpretation means, unless specified otherwise, as amended, modified, codified, replaced or re-enacted, in whole or in part, and in effect on the determination date, including rules, regulations and applicable guidance promulgated thereunder;

(d) "hereunder", "hereof", "hereto", "herein" and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Article, Section or other provision hereof; and "including" (and with correlative meaning "include") means including without limiting the generality of any description preceding such term.

11.2 Independent Contractors . It is expressly agreed that GenMark and Plexus shall be independent contractors and that the relationship between the parties shall not constitute a partnership, joint venture or agency. Neither GenMark nor Plexus shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the party to do so.

11.3 Notices . Any consent, notice or report required or permitted to be given or made under this Agreement by one party to the other shall be in writing, addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective: (a) if sent by registered or certified mail in the United States return receipt requested, upon receipt; (b) if sent by nationally recognized overnight air courier (such as DHL or Federal Express), two (2) business days after mailing; and (c) if otherwise actually personally delivered, when delivered.

If to GenMark: GenMark Diagnostics, Inc.
5964 La Place Court
Carlsbad, California 92008
Attention: Chief Executive Officer
Copy to: General Counsel

If to Plexus: Plexus Corp.
One Plexus Way
Neenah, Wisconsin 54956
Attention: Executive VP & Chief Customer Officer
Copy to: General Counsel

11.4 Noninterference . Plexus represents and warrants that no provision of this Agreement is in any way in conflict with or impairs the performance of any present contractual obligation to any third party and neither Plexus nor any persons employed by Plexus or who assist Plexus in this project will assume any obligation or restriction which will conflict with or prevent them from performing any of the services contemplated by this Agreement.

11.5 Assignments, Succession and Waivers . Neither this Agreement nor any part thereof shall be assignable by the other party without the express written consent of the other party, and any attempted assignment shall be null and void, *provided, however* , that either party may assign this Agreement to an Affiliate of such party or to a Person that succeeds to all or substantially all of that party's business or assets whether by sale, merger, operation of law or otherwise. This Agreement shall be binding upon and shall inure to the benefit of the parties, their successors and permitted assignees. No express waiver or any prior breach of this Agreement shall constitute a waiver of any subsequent breach hereof and no waiver shall be implied.

11.6 Force Majeure . If the performance of this Agreement or any obligations hereunder is prevented, restricted or interfered with by reason of fire or other casualty or accident, strikes or labor disputes, war or other violence, any law, order, proclamation, ordinance, demand or requirement of any government agency, or any other act or condition beyond the control of the parties hereto (" **Force Majeure** "), the party so affected, upon giving prompt notice to the other party shall be excused from such performance during such prevention, restriction or interference. If the Force Majeure continues for more than *** , then the other party may by written notice to the affected party terminate this Agreement.

11.7 Integration . This Agreement (together with the Exhibits, Schedules and Appendices hereto), expresses the entire understanding between GenMark and Plexus with respect to the subject matter hereof and merges all prior oral discussions or written correspondence between them, except that the rights and obligations contained in any confidentiality agreement(s) executed by the parties prior to the Effective Date shall not be deemed waived, amended, superseded or otherwise affected hereby. No notification, extension, amendment or waiver of this Agreement or any provision hereof shall be binding unless agreed to in writing by the parties.

11.8 Governing Law . This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

11.9 Legal Counsel . Each party is a sophisticated business entity which has involved legal counsel of its own choosing in drafting, negotiating and concluding this Agreement and any presumption in statutory or common law against the drafter of

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any particular provision herein, or against the drafter of this Agreement as a whole, shall be of no effect whatsoever and each party shall refrain from asserting or relying upon any such presumption.

11.10 Affiliate Performance . Either party may perform all or part of its obligations hereunder, and may exercise any of its rights hereunder, by or through any Affiliate of the party; provided that nothing herein shall relieve such party of its obligations hereunder unless expressly authorized by the other party in writing.

11.11 Severability . If any provision of this Agreement is held unenforceable or in conflict with applicable law, it is the intention of the parties that the validity and enforceability of the remaining provisions hereof shall not be affected thereby.

11.12 Headings . All article and section captions or titles are intended only for reference purposes and are without contractual significance or effect.

11.13 Counterparts . This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, but all of which together will constitute one and the same instrument; however, this Agreement shall have no force or effect until executed by both parties.

[**Remainder of Page Left Intentionally Blank**]

IN WITNESS WHEREOF , the parties hereto have executed this Agreement as of the Effective Date:

CLINICAL MICRO SENSORS, INC. D.B.A GenMark DIAGNOSTICS, INC.	**Plexus Corp.**
By: /s/ Hany Massarany	By: /s/ Steven J. Frisch
Name: Hany Massarany	Name: Steven J. Frish
Title: Chief Executive Officer	Title: Executive VP & Chief Customer Officer

Exhibit A
Quality Agreement

Quality Assurance Agreement
Between Plexus and GenMark

Contents

Note: This quality assurance agreement was written so that Article I contains general information to the supplier. Article III states requirements applicable to every supplier regardless of the ***product*** purchased by GENMARK. Then each of the following articles contains additional requirements depending on the ***product*** purchased.

E. Calibration records.
F. Notification to GENMARK.
G. Use of calibration lab.

5. GENMARK right to inspect (Audit)
A. Supplier’s executive management responsibility.
B. GENMARK Audits.
C. Third party audit.

6. Corrective and preventive action (CAPA)
A. Basic CAPA requirements

Annex I. Specific Requirements for Manufacturing
1. Receiving, receiving inspection, and storage
A. Authorized receipts.
B. Direct to stock receipts.
C. Receiving inspection.
D. Storage.

2. Production and process controls
A. Engineering drawings.
B. Inspections and tests.
C. Standard operating procedures.
D. Production controls.

4. Calibration of inspection, measurement and test equipment
A. Calibration requirements.
B. Calibration procedures.

5. GENMARK right to inspect (Audit)
A. Supplier’s executive management responsibility.
B. GENMARK Audits.
C. Third party audit.

6. Corrective and preventive action (CAPA)
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B. Inspections and tests.
C. Standard operating procedures.
D. Production controls.
E. Automated test systems.
F. Process validation.
G. In-process rejects.
H. Statistical applications.
I. Environmental controls.
J. Equipment maintenance.
K. Final acceptance activities.
L. Production history records.

3. Storage, packaging and transport

4. Nonconformances
   A. Control of nonconforming articles.
   B. Control of nonconforming product.
   C. Rework of nonconforming product.
   D. Product returns.
   E. Product salvaging.

5. Processing product changes of manufactured product
   A. Processing product changes initiated by the supplier.
   B. Implementing product changes initiated by the supplier.
   C. Processing product changes initiated by GENMARK.
   D. Supplier implementing changes initiated by GENMARK.

Annex II. Specific Requirements for
Warehousing/Distributing Product for GENMARK
   A. Handling.
   B. Storage.
   C. Product packaging.
   D. Distribution.
   E. Distribution records.
   F. Product recall, field corrections, modifications, updates.
   G. Environmental controls.

Annex III. How GENMARK Evaluates It’s Suppliers
   A. Introduction.
   B. Details of the GENMARK Evaluation System.

Article I. Purpose (Informative)

1. Introduction

Medical device manufacturers, such as (GENMARK), are obligated to follow many regulations and standards relating to product quality which may include, but are not limited to, the following:

- TITLE 21 Code of Federal Regulations Part 820 - Quality System Regulation
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVD Directive)
- ISO 13485:2003 Medical Device Quality Management System
- ISO 9001:2008 Quality Management Systems

In general these regulations prescribe what medical device manufacturers must do during design, manufacturing, and post-manufacturing. While they do not directly apply to suppliers of medical device manufacturers, it is the responsibility of GENMARK and other medical device manufacturers to assure that only product conforming to specified requirements is used.

These regulations explicitly require that the finished device manufacturer assess the capability of suppliers to provide quality products and services. Because of the complexity of the many parts used in GENMARK devices, their adequacy cannot always be assured through inspection and testing by GENMARK. Quality must be assured through the application of proper quality systems.

As medical device and diagnostics products become more complex and as demand increases, the chance of errors and inconsistencies in manufacturing escalate. Only by implementing systematic processes and quality controls during the product life cycle (e.g.: design, manufacture, installation and service) can manufacturers like GENMARK eliminate variability that can lead to regulatory actions, devastating product recalls, and lost market share. Therefore, GENMARK expects that all of our suppliers will collaborate with GENMARK and support our effort in meeting our obligations for medical device manufacturers.

2. Quality system requirements in general

GENMARK requires that our suppliers establish and maintain a quality management system that is appropriate for the specific product being manufactured or the service performed that ensures the users of GENMARK products receive and operate safe, effective, and reliable medical equipment.

GENMARK expects its suppliers to have processes that ensure that they meet the quality system requirements specified herein. It also recognized that some suppliers are small businesses while others are large corporations. Exactly how a supplier establishes and maintains their quality system to meet GENMARK' requirements is dependent upon the supplier's operation and is appropriate for the business size of the supplier provided that quality, reliability, maintainability and regulatory requirements are maintained at the highest level.

In this document, a ***requirement*** means a specification or characteristic with which a product, process, service, or other activity being performed for GENMARK must conform. ***Product*** means component, material, substance, piece, part, software, firmware, assembly, and finished device to be used in or with a finished medical device, or a service performed to design, develop, install, repair, or maintain a finished medical device and its accessories.

These requirements have been established in order to assist GENMARK in meeting our obligations for safety, quality, and reliability.

3. Notes regarding regulations and standards

A. FDA regulations. Manufacturers that are registered with FDA as a device manufacturer or as a contractor which manufactures and supplies GENMARK with accessories that function with GENMARK equipment are expected to follow all applicable FDA regulations in addition to the requirements herein. Non-medical device manufacturers that supply accessories that function with GENMARK equipment or other products are expected to follow all of the requirements herein, as appropriate.

B. IVD Directive (Directive 98/79/EC). All medical devices sold within the EU member states must meet certain essential safety and administrative requirements, defined in the IVD Directive, before they can be marked with the applicable CE mark by the manufacturer.

C. ISO standards. GENMARK does not mandate that all of it suppliers be certified to an ISO standard. However, if an ISO certification does exist, the supplier shall meet the standard's requirements. The requirements given herein will be used by GENMARK when evaluating the effectiveness of a supplier's quality management system (QMS).

Article II. Scope

This quality assurance agreement (QAA) applies to the manufacture and delivery of products to GENMARK by the supplier. When this annex is blank or does not reference the Scope of Work, then this QAA applies to all products procured by GENMARK from the supplier.

1. Applicable Products

This Quality Assurance Agreement (QAA) applies to the following product(s) delivered by the supplier to GENMARK. If nothing follows, then the QAA applies to all products ordered by GENMARK.

2. Additional Requirements Not Stated in the QAA

The following special requirements (barcoding, product labeling, testing, inspection, packaging, documentation, etc.) are in addition to the QAA. If nothing follows, then there are no additional requirements not stated in the QAA.

3. Exclusions to the QAA

The following are exclusions to the QAA as agreed to between GENMARK and the supplier. If nothing follows, then there are no exclusions to the QAA. This QAA is specific to the manufacturing of the

Article III. Quality Assurance Requirements Applicable to All Suppliers

1. Quality system

A. Establishment. It is expected that the seller has established and is maintaining a quality management system that is commensurate with the *product* being provided to GENMARK or in support of GENMARK' business. It is further expected that the supplier's quality system has been established to ensure that all GENMARK requirements are understood and are being met.

For the exchange of quality-relevant information between the parties via e-mail, appropriate software for electronic signature and encryption has to be used, where appropriate.

B. GENMARK requirements. The supplier is required to ensure that it has received and understands all requirements received from GENMARK in writing.

C. Deviations. The supplier shall receive written authorization from a representative of GENMARK prior to making any changes to any GENMARK requirement, including the requirements herein. Failure to comply with this GENMARK requirement could have a serious impact resulting in the GENMARK medical device becoming adulterated within the meaning of U.S. Federal Regulations.

D. Process control plan. The supplier shall: (a) define and document (i.e. in a process map, in a flow diagram, or etc.) the processes it uses, from order receipt to order fulfillment, necessary to provide the product for GENMARK; (b) verify that these processes are effective in producing the desirable product for GENMARK, (c) establish the methods to appropriately monitor, measure and control these processes to ensure that product requirements are consistently meeting GENMARK' requirements; and (d) provide, when appropriate, for a means to analyze process trends and take prompt action to correct any unfavorable trend.

E. Quality system procedures. The supplier shall have documented procedures and instructions to effectively implement the established quality system and support the process plan.

F. GENMARK owned property. The supplier is responsible for identifying, controlling, maintaining, storing, and, where appropriate, calibrating GENMARK owned property. The supplier is required to timely notify GENMARK in the event that any GENMARK property is lost or damaged, or that its continued use could result in nonconforming product.

This includes, but not limited to, meters, gages, tools, fixtures, instruction manuals, installation aids, and software provided by GENMARK to the supplier to provide product to GENMARK.

The use of such property is limited to making/providing product for GENMARK and may not be used by the supplier for any other purpose without written approval from an agent of GENMARK.

GENMARK will reimburse Plexus for expenses associated with maintaining and as appropriate calibrating GENMARK owned property in accordance with section 4.1 of the Agreement.

GENMARK will provide Plexus with sufficient information to verify, calibrate, operate, test and maintain any GENMARK supplied property.

G. Complaints from GENMARK customers. While it is reasonable to expect that the supplier will have some interaction with a customer of GENMARK, the supplier is required to have a written procedure for forwarding to a representative of GENMARK, without undue delay, any written, electronic, or oral communication from a customer of GENMARK that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any of GENMARK equipment.

GENMARK is responsible for all complaint handling in accordance with section 3.11 of the Agreement.

H. Complaints from GENMARK . The supplier is to establish a process for receiving a complaint from GENMARK alleging nonconformity of the supplier's product and providing timely feedback to GENMARK reporting on the corrective action it has taken or rationale for not taking corrective action.

The supplier shall have a written procedure describing the corrective action process. The procedure is to include:
1. the department or staff responsible for receiving, reviewing, evaluating and coordinating complaints from GENMARK
2. documenting oral complaints upon receipt,
3. processing complaints in a timely and uniform manner,
4. the investigation process to determine the root cause of the problem,
5. evaluating the need for action to ensure that the problem does not recur,
6. determining and implementing the action needed to provide a solution to the problem,
7. action on product already delivered and/or other sites or systems that could be affected by the nonconformity,
8. verification of activities to show that the actions taken were effective,
9. management review and approval of the action taken, and
10. maintaining records of corrective actions. Corrective action records are to be made available to GENMARK upon request.

I. Management representative. The executive management is to appoint a member of management who, irrespective of other responsibilities, is the supplier's management representative for quality. This manager shall have the overall responsibility and authority to ensure that the quality system is effectively established and being maintained. This individual must be available to be contacted by a representative of GENMARK whenever issues of product quality arise.

J. Personnel training. The supplier is responsible for maintaining sufficient personnel with the necessary education, background, training, and experience to assure that the established quality system and process plan are correctly implemented. Personnel are to be adequately trained and qualified to perform their assigned responsibilities according to an established training plan. Untrained, unqualified personnel are only to perform work while under the supervision of qualified personnel so they do not damage or otherwise cause harm to the product. The supplier shall also ensure that its personnel receive up-to-date retraining, as appropriate, whenever processes, methods, technology or other changes reasonably suggest that retraining is necessary. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the requirements of the established training plan and these records are to be made available to GENMARK upon request.
1. **Blood borne pathogens** . Where it is reasonable to expect that personnel might come into contact with used medical devices of any kind, the supplier is responsible for training their personnel in the OSHA regulations for blood borne pathogens. This includes returning component parts for failure investigation or complaint processing. (See www.osha.gov for further information)

2. **HIPAA** . Where it is reasonable to expect that employees or agents of the supplier might have access to patient records, either by need or accidentally, the supplier must comply with the Health Insurance Portability and Accountability Act (1996) to maintain the confidentiality and privacy of any such patient information. (See www.hhs.gov/ocr/hipaa for more information.)
3. **ESD.** Where it is reasonable to expect that electro-static discharge (ESD) could affect the requirements of product, including product being returned to GENMARK for failure investigation, supplier shall ensure that their personnel are trained in ESD controls, including handling and packaging.

K. Changes to quality system or product. The supplier's executive management is responsible for notifying GENMARK of any change (prior to implementation) to the product, including the process plan, when the change could affect product quality, so that GENMARK may determine whether the change affects the quality, reliability, safety, or efficacy of the finished medical device. The supplier shall have a documented process identifying how it will inform GENMARK of any such quality system and product changes.

2. Control of documents and records

A. Control of documents. Documents required by the quality system are to be controlled according to a written procedure. These include, for example, procedures, drawings, instruction manuals, service manuals, test methods, inspection instructions, specifications, and product literature.

B. Reserved.

C. Change control. Changes (revisions) to documents are to be reviewed and approved by personnel who are as capable as the original reviewers and approvers.
1. Changes to documents are to be timely communicated by the supplier to appropriate personnel.
2. The supplier must establish and maintain a system to receive GENMARK document revisions and implement these revisions in a timely manner.
3. Suppliers are not permitted to accept and act on verbal change requests from GENMARK and GENMARK is not permitted to provide verbal change requests to Supplier.

D. Availability of documents. Documents are to be readily available to the supplier's personnel at their intended point-of-use.

E. Control of records. Records are a special type of document. Records are typically completed forms, checklists or other evidence that demonstrate that requirements have been met and the effective operation of the quality system. Records are to remain legible. Records are to be controlled according to a written procedure which shall include the controls needed for the identification, storage, protection and disposal. Records are to be retained for at a minimum of 10 years. A copy of a record(s) is to be made available to GENMARK within 2 business days of request. Additionally, the provisions for archiving device specific documents shall survive the termination of the QAA.

Following expiration of the retention periods, the supplier shall offer to transfer device specific records to GENMARK free of charge.

F. Electronic documents and records. Where electronic systems are used for the control of documents, the system must be validated to ensure that only approved documents are made available at the point-of-use, write protection is provided, and approval forgery is prevented. Where records are stored electronically, the system shall have appropriate controls to ensure that only true copies of records are stored and controls in place to preclude unauthorized changes and loss.

3. Purchasing controls

A. Approval of subtier suppliers. The supplier is to evaluate their own suppliers to the extent necessary to ensure quality products are being provided. Approvals of subtier suppliers are to be based on this evaluation. The supplier shall establish and maintain an approved supplier list. In the event that GENMARK has provided an approved supplier list to the supplier, any deviations must be approved by GENMARK prior to purchase of any product. Controls are to be in place to assure that purchases are only made from approved suppliers.

B. Specific GENMARK requirements. When the GENMARK engineering drawings or other GENMARK document specifies the subtier supplier to be used, the supplier is to ensure that these requirements are followed. GENMARK specified subtier suppliers are to be added to the supplier's approved supplier list. No substitutions or alternates to a specified subtier supplier are to be made without written consent from an authorized representative of GENMARK.

C. Quality control of 3 rd party products
The supplier is responsible for assessing the quality system and for the quality of product received from all third-party suppliers it uses.

If the supplier receives production or test equipment, software, services, materials or other supplies from third parties for the manufacture or quality assurance of its products, the supplier shall ensure that these are in compliance with its quality management system, whether it be by contract with these parties or through carrying out such tests itself as are necessary to assure compliance with its quality management system.

D. Purchase information. Purchase orders shall include adequate information, including quality requirements, so as to be precise and unambiguous as to what is being purchased.

E. Traceability. GENMARK shall define any "critical" components requiring component level traceability. GENMARK shall also select the appropriate component level or device level traceability grade, in order to meet any applicable FDA requirements or regulations. Plexus is responsible for implementing the defined manufacturing-level traceability requirements and for ensuring that the appropriate manufacturing-level traceability records and associated records are retained for the duration of this Agreement.

4. Calibration of inspection, measurement and test equipment

A. Calibration requirements. Any equipment used to establish product specifications during design and development, used to determine process parameters, or used to judge the acceptability of a product specification shall be maintained under a calibration program.

B. Calibration procedures. Procedures shall be established and maintained to ensure that inspection, measuring, and test equipment (IM&TE) used to determine the acceptance or rejection of process or product requirements during design, production, installation or service are calibrated, inspected, checked and maintained in accordance with the manufacturer's recommendations. Calibration procedures shall include specific directions and limits for accuracy and precision. Calibration standards used for IM&TE must be in conformity to national or international standards.

C. Suitability of equipment. Suppliers shall ensure that all IM&TE, including mechanical, automatic, or electronic inspection and test equipment, are suitable for their intended use and capable of producing valid results. Controls shall be in place to ensure that IM&TE maintain their suitability while in-use, in transit, or in storage.

D. Calibration labeling. A label is to be affixed on or, if appropriate, near the IM&TE. This is to inform the user of the IM&TE that the IM&TE is under the calibration program. The label is to include: (a) date IM&TE was calibrated, (b) who performed the calibration, and (c) the due date of the next calibration.

E. Calibration records. Supplier is responsible for maintaining records to provide objective evidence that IM&TE are being maintained and calibrated. These records shall be made available to GENMARK upon request.

F. Notification to GENMARK. The supplier shall notify GENMARK without undue delay when the supplier becomes aware of the use of any inappropriate or out-of-calibration inspection measurement and test equipment so that GENMARK can evaluate the effect of its use and any necessary corrective or other action, up to and including reworking at the supplier's expense.

G. Use of calibration lab. When the supplier uses the services of an outside calibration service, it is the responsibility of the supplier to ensure that the service provider meets any and all requirements for the service provided.

5. GENMARK right to inspect (Audit)

A. Supplier's executive management responsibility. To ensure the effectiveness of the supplier's quality system to deliver conforming product, GENMARK may require representatives of GENMARK to perform quality system audits at the supplier's facility. The supplier's executive management shall support such audits and ensure that prompt corrective actions are taken to address any discrepancies found.

B. GENMARK Audits. The supplier shall at reasonable intervals allow GENMARK to check the compliance with this quality assurance agreement. The supplier shall therefore, after prior agreement of the parties on the date of such an inspection,

grant GENMARK reasonable access to its business premises and shall make available a duly qualified member of its staff for the duration of the inspection visit. GENMARK may be denied access to and inspection of classified manufacturing methods and other industrial secrets.

This described right of GENMARK includes the right to inspect the existing documentation and to participate in quality checks carried out by the supplier. The checks may be carried out by way of quality audits (e.g. audits involving the systems, products or processes) and via inspections.

C. Third party audit. An audit or regulatory inspection may also be required from time to time. This may involve the authority having jurisdiction over GENMARK according to the European IVDD 93/42/EEC or any other regulatory authority (e.g., US Food and Drug Administration) or authorized organization or by third parties commissioned by GENMARK.

6. Corrective and preventive action (CAPA)

A. Basic CAPA requirements. The suppliers shall establish procedures for implementing corrective and preventive action. The procedures shall include requirements for:

1. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed, where necessary, to detect recurring quality problems;
2. Investigating the cause of nonconformities relating to product, processes, and the quality system;
3. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
6. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems;
7. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review; and
8. Ensuring that all activities required under this section, and their results, are properly documented.

Annex I. Specific Requirements for Manufacturing

NOTE: This section applies to suppliers producing, assembling, fabricating or processing product for GENMARK.

1. Receiving, receiving inspection, and storage

A. Authorized receipts. The receiving function shall ensure that only deliveries from 3 rd party suppliers that are listed on the supplier's approved supplier list are accepted and processed. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix-ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.

B. Direct to stock receipts. When received articles bypass receiving inspection and go directly to storage or to their point-of-use, controls must be in place to avoid mistakes and the unintentional acceptance of articles.

1. The acceptance of these articles must have some form of prior documented approval, including the rationale, to bypass receiving inspection.
2. The receiving function shall record the acceptance of the articles after verifying they meet predetermined requirements.

C. Receiving inspection. Receiving inspection activities shall be established and maintained in a written procedure. These activities are to confirm or to otherwise verify that incoming articles conform to specified requirements. When other than 100% inspection is performed, the sample size is to be determined based on the risk of accepting the lot when it should have been rejected. Only published sampling plans may be used (i.e., ANSI/ASQC Z-1.4). Receiving inspections are to be recorded and include (1) the inspection/tests performed, (2) date inspection/tests were performed, (3) results -acceptance or rejection, (4) the signature of the inspector, and (5) where appropriate, the test equipment used. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.

D. Storage. Stockrooms, where materials and parts are stored for later use in production, are to be kept orderly and well maintained. Only items that have been accepted for use are to be stored in the stockroom. All bins, cartons, or other containers holding the items in storage are to be labeled with the item's part number and be of such design as to preclude mix ups.

Controls are to be in place to prevent damage and deterioration while items are in storage. Controls for temperature sensitive and limited shelf life materials must be considered.

2. Production and process controls

A. Engineering drawings. In cases where the supplier receives GENMARK engineering drawings and then imports them into the supplier's engineering drawing format for internal use, confidentiality of both sets of drawings is to be maintained. Both sets of drawings are to remain the property of GENMARK.

B. Inspections and tests. Whether required by GENMARK or not, the supplier is responsible for conducting all appropriate inspections and tests that are necessary to confirm that the product made for GENMARK meets all of its specified requirements and quality attributes.

C. Standard operating procedures. Production operations are to be defined, conducted, controlled, and monitored to the extent necessary to ensure that the product made for GENMARK conforms to its specifications. This is to be documented in standard operating procedures (SOP's).

D. Production controls. A process control plan (or similar document) shall be established and maintained that outlines the various production operations and the process controls necessary to manufacture acceptable product for GENMARK, if not already detailed and included in the process plan. The following is a list of items that must be considered for inclusion in the process control plan, dependent upon, and where appropriate for, the complexity of the process(es) used to manufacture product for GENMARK.

1. The controls to assure only accepted process inputs are used. Inputs are the materials and parts needed to make the product.
2. Clear identification (labeling) and separation of the materials and parts stored on the production floor in order to prevent mix ups and their unintended use.
3. Controls to prevent the use of materials that have exceeded or are nearing their expiration date.
4. The process to ensure the production line has been cleared of inputs from previous production runs for a different product (i.e., a "line clearance").
5. The assignment of a unique lot or batch number, or date code, to the production run for future reference and record keeping.
6. The manufacturing steps required (i.e., the use of a route tag).
7. The criteria for workmanship, including representative samples.
8. The process characteristics (parameters) to be controlled during production.
9. The means, such as SPC, for the continuous monitoring and control of critical-control-points in the production processes.
10. The in-process product attributes that are critical to quality are monitored during production.
11. The defined acceptance and rejection criteria of the process output to ensure that they are correctly inspected/tested by qualified individuals.
12. Controls for the handling and reworking of in process nonconformances.
13. The final inspection and test methods to be used for product release.
14. Handling procedures to assure that personnel handling and moving both in-process and final product do not inadvertently cause nonconformances.
15. The procedure for adequately packaging the product for shipment to GENMARK so that it is reasonable to expect that product quality will not be affected during transportation.
16. The method for recording process data and inspection/test results either electronically or on paper forms.

E. Automated test systems. Software controlled and/or automated test systems used to determine the acceptance or rejection of incoming product, in-process product or final product are to be validated or otherwise verified to assure that consistent and repeatable results are obtained and that the system is fit for its intended use.

F. Process validation. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated. Processes that typically require validation include, but are not limited to:
Reflow & wave soldering
Injection molding
Plating
Bonding
Sterilization

GENMARK shall be responsible for the software validation (current and future revisions) of any embedded product software and the validation of all GENMARK -supplied: (1) test equipment or test software; (2) production equipment or software; and

(3) firmware. Plexus is responsible for the validation of any Plexus software used in production in, or as part of its quality system.

G. In-process rejects. Supplier is to establish and maintain procedures to ensure that the causes of internal, in-process rejects are identified and corrected so as to prevent their recurrences. Where appropriate, supplier shall monitor (i.e., trend chart analysis) production operations to enable the early detection of problems and correct them in order to prevent rejects from occurring.

H. Statistical applications. Valid statistical techniques shall be used, where appropriate, for the verification of the acceptability of incoming product, process characteristics, and product release.

I. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.

J. Equipment maintenance. Production equipment is to be maintained to ensure its continuing suitability and capability to manufacture acceptable output.

K. Final acceptance activities. Product shall not be released for shipment until all requirements have been confirmed as being satisfactorily completed, unless otherwise approved in writing by GENMARK. Records shall include the signature of the person(s) authorizing release of the product. Prior to shipment, the supplier shall confirm and document that the product meets all of its requirements. This verification is to include the following items.

1. The GENMARK part number and revision level to be shipped is what was ordered.
2. The process control plan was followed. All in-process inspection and tests and final inspections and tests were completed and their results are acceptable.
3. All required forms and other documents are available and correctly completed.
4. Any necessary documents to be shipped with the product, such as a certificate-of-conformance, are complete and ready to go.

L. Production history records. Records, including route tags, process forms, inspection forms, and test data forms, are be maintained to demonstrate that the product was produced according to the production control plan.

3. Storage, packaging and transport

The supplier shall ensure that sufficient protection is given for storage on its own premises, in particular against damage and environmental influences. GENMARK is responsible for defining and validating the finished device packaging. GENMARK will provide Plexus with written certification that the packaging validation has been performed prior to the production of the devices.

To the extent the parties do not have any other agreement relating thereto, the products shall be packaged and transported in a defined and reproducible manner at the supplier’s responsibility. The supplier shall thereby ensure that the packaging units are clean, that there is sufficient protection in place against damage and that the transport security in place is capable of maintaining the quality requirements.

As far as possible, the environmental impact of packaging and transportation of newly produced products by way of coordinated forwarding concepts with multiple and/or shuttle packaging, the reduction of the packaging volume and use of environmentally friendly packaging materials, as well as the costs of packaging and disposal, are to be optimized.

With regard to packaging repaired used products and spare parts, single shipment packages are to be used that can only be opened by way of a sealed closure, and which are suitable with regard to providing effective protection against transport-related changes in the case of worldwide shipment. The possibilities with regard to reducing the amount of packaging, and the use of environmentally friendly materials and reusable packaging, are to be utilized insofar as such course of action is also possible within this framework.

4. Nonconformances

A. Control of nonconforming articles. Nonconforming articles (raw materials, parts, piece parts, in-process work, etc., used to produce product for GENMARK that do not meet specified requirements) are to be rejected, labeled as such, and separated to preclude their accidental use. Nonconforming articles can only be used to produce product for GENMARK after they have

been reworked to meet original specifications, or with written (e.g., deviation) authorization from GENMARK.

B. Control of nonconforming product. Product made for GENMARK that failed to meet its specified requirements and quality attributes shall be rejected, labeled as such, and separated so as to prevent it from being shipped to GENMARK. Supplier shall not knowingly ship nonconforming product to GENMARK without first receiving written authorized approval from GENMARK.

C. Rework of nonconforming product. Nonconforming product may be reworked provided these operations are carried out according to written procedures and are carried out by personnel having the necessary knowledge and skill sets to perform the rework. Reworked product must be re-inspected and re-tested, and pass all originally specified requirements and quality attributes. The rework operations, including the reinspection and retests, are to be recorded.

D. Product returns. Suppliers must have a procedure for receiving returned product from GENMARK in the event it is rejected. The supplier's procedure should include verification of the nonconformance. If the nonconformance cannot be verified, for whatever reason, the supplier shall promptly notify GENMARK and work toward a resolution. When the nonconformance is confirmed by the supplier, appropriate corrective action is to be taken to address and correct the problem. This action may include:

1. Confirming that the correct process inputs were used.
2. Confirming there was an adequate "line clearance" before making the product for GENMARK.
3. Verifying personnel are adequately trained and have the necessary skill sets.
4. Changing the process plan (i.e., increasing in-process and/or final inspections and tests, moving controls upstream in the process for earlier detection of problems, instituting new inspections or testing, etc.).
5. Modifying the production control plan (i.e., increased in-process monitoring of process parameters).
6. Reworked or returned product subsequently reshipped to GENMARK is to be clearly labeled or otherwise identified as being reworked or repaired, and packaged in all new materials.

E. Product salvaging. New products may only contain components drawn from used products if expressly approved by GENMARK.

5. Processing product changes of manufactured product

The supplier shall document all product changes in accordance with its quality management system. This includes, but is not limited to, product changes that could have an effect on product function; design; acceptance; interfaces; transport and storage capabilities; handling; capabilities regarding processing, repairs or maintenance; production processes; recycling or the disposal of products as well as all changes to documents that are distributed with the products (e.g. data sheets, operating manuals or maintenance instructions).

A. Processing product changes initiated by the supplier. All product changes by the supplier are subject to written approval by GENMARK. For approval, the supplier shall forward to GENMARK a written change inquiry, which shall address the following points:

- Products and product characteristics affected
- Exact description of required change
- Consequences of product change from the supplier's point of view (including risks)
- Required start of product change (e.g. from serial number, batch number, order or date).
- GENMARK shall assess the required product change and provide the supplier with written authorization, which may be subject to further requirements.

B. Implementing product changes initiated by the supplier. The supplier shall only implement the changes following the receipt of the written authorization by GENMARK of the changes and the implementations of any further requirements contained therein, and provide notification of the conclusion of the implemented changes in the form of a written confirmation to GENMARK.

Following the successful validation of the change, at the supplier's premises or, if necessary at GENMARK' premises, the delivery of the changed products shall be released in writing by GENMARK.

The start of the delivery of changed products shall be agreed upon in writing.

C. Processing product changes initiated by GENMARK. If GENMARK requests a change in the product, GENMARK shall forward a written change inquiry to the supplier, which shall address the following points:

- Products and product characteristics affected
- Exact description of required change
- Consequences of product change from GENMARK point of view (including risks)
- Required start of product change (e.g. from serial number, batch number, order or date).

The supplier shall review the degree to which the requested changes can be realized and the consequences, and inform GENMARK of the outcome of such a review in the form of a written offer.

Following the review of such an offer, GENMARK shall issue the supplier with a written change order, including the respective validation requirements. Within such a change order the costs and the release regarding the manufacture of an initial batch or a prototype shall be agreed upon.

D. Supplier implementing changes initiated by GENMARK. The supplier shall implement the product change following the receipt of the written change order and the parameters specified therein by GENMARK, and provide notification of the conclusion of the implementation of the change in the form of a written change confirmation. The supplier shall furthermore make available to GENMARK prototypes of the changed products against reimbursement of its costs if this is necessary for further validation at GENMARK' premises.

Following the successful validation of the product change, at the supplier's premises or, if necessary at GENMARK' premises, the delivery of the changed products shall be released in writing by GENMARK.

The start of the delivery of the changed products shall be agreed upon in writing.

In the event of any conflict between this Section 5 of the QAA and the Supply Agreement, the Supply Agreement shall control.

Annex II. Specific Requirements for Warehousing/Distributing Product for GENMARK

A. Handling. The supplier shall have controlled processes to ensure that only product authorized by GENMARK is received, stored and distributed. The process is to include a method that prevents mix-ups, damage, deterioration, contamination, or other adverse effects from occurring to product during handling. Records of receipts, including the date and name of person accepting the receipt, shall be maintained.

B. Storage. The supplier shall have processes that ensure control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

C. Product packaging. The supplier is responsible for and shall ensure that device packaging and shipping containers are used to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

D. Distribution. The supplier shall control the distribution of product to ensure that only product approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before products are released for distribution. Where a product's fitness for use or quality deteriorates over time, the controls shall ensure that expired products are not distributed.

E. Distribution records. The supplier shall maintain distribution records and make them available to GENMARK upon request. Records are to include:
1. The name and address of the initial consignee;
2. The identification and quantity of devices shipped;
3. The date shipped; and any control number(s) used.

F. Reserved.

G. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.

Annex III. How GENMARK Evaluates Its Suppliers

A. Introduction. Those suppliers identified based on annual spend or those suppliers whose products and/or services are critical to the safety, efficacy, and reliability of the medical devices GENMARK manufactures, will be deemed "Class 1suppliers, and will be evaluated by GENMARK in accordance to GENMARK Quality Procedure QP0800.

B. Details of the GENMARK Evaluation System.

1. **Purchasing**
    a. **Total Cost Performance**
        i. Are supplier's prices competitive?
        ii. Payment terms
        iii. Additional procurement costs
    b. **Cost Reduction Efforts**
        i. Cost reduction efforts within existing designs
    c. **Fulfillment of Strategic Requirements**
        i. The market strategy of the supplier
        ii. How is the supplier's economic situation?
        iii. How is the conduct during contract negotiations?
        iv. Supplier is registered in Click4Suppliers (c4s)
        v. Does the supplier offer an Open Book Policy?
    d. **Co-Operation, Service, & Support**
        i. Cooperation, Service, & Support
2. **Quality**
    a. **Quality Performance**
        i. Product Acceptance Quality Performance (includes Receiving, In Process, Service, Reporting and Documentation, Packing, etc.)
        ii. Field Quality Performance After Delivery (or similar measure; e.g. Open MPSR ratio)
    b. **Quality System**
        i. Does the supplier have a Quality Management System (QMS) which meets the requirements of GENMARK or the business unit?
        ii. Quality Management System, audit findings
        iii. Number of corrective and preventative action (CAPA) or supplier development plans
    c. **Quality Assurance Agreements (QAA)**
        i. QAA in place or part of the frame contract, as appropriate
    d. **Co-Operation, Service, & Support**
        i. Cooperation, Service, & Support
3. **Logistics**
    a. **Logistics Performance**
        i. Does the supplier meet targeted delivery/milestone dates?
        ii. How good is the response time to delivery problems
        iii. Delivery flexibility
    b. **Logistics Strategy and System**
        i. Does the supplier offer logistics models which meet the needs and requirements of the business unit
        ii. Interface connection
    c. **Environmental Aspects**
        i. Does the supplier have an EMS which systematically advances the improvement of environmental protection and keeps GENMARK informed about current actions for environmental protection?
        ii. Does the supplier meet the requirements of the ecological product/service design, packing, and logistics?
        iii. Documentation of hazardous materials
    d. **Co-Operation, Service, & Support**
        i. Cooperation, Service, & Support
4. **Technology**
    a. **Current technology positio** n
        i. Product technology ("Product" also means Service and Software)
        ii. Engineering capability and competence
        iii. Engineering documentation
        iv. Technical equipment and facilities

b. **Fulfillment of specific technical requirements**
    i. Prototypes and engineering samples
    ii. Supplier communication and support of changes
c. **Fit of technology roadmaps**
    i. The supplier's technology roadmap includes research, design, manufacturing processes, environmental health and safety characteristics
d. **Co-Operation, Service, & Support**
    i. Cooperation, Service, & Support
    ii. Support of manufacturing and/or sustained engineering

IN WITNESS WHEREOF , the parties hereto have executed this Quality Agreement as of the Effective Date:

CLINICAL MICRO SENSORS, INC.
D.B.A GenMark DIAGNOSTICS, INC.

By: /s/Tho Tran
Name: Tho Tran
Title: Director Quality Assurance

By: /s/ Al Maderazo
Name: Al Maderazo
Title: VP QA and Regulatory Affairs

Plexus Corp.

By: /s/ Andrew Steinhaus
Name: Andrew Steinhaus
Title: Quality Engineer

By: /s/ Bruce Schullo
Name: Bruce Schullo
Title: Mgr - Regulatory Compliance

Exhibit B
Specifications

Document No.	Description
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*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

Exhibit C
Products and Pricing

Effective Date Beta Pricing

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Production Product Pricing Criteria

The parties agree that:

Prior to manufacturing Product production units under this Agreement and consistent with past practice, Plexus will provide GenMark with *** . (collectively, the " **Pricing Criteria** ").

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.

Spare Parts

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Exhibit D
GenMark Equipment

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Exhibit 10.23

GENMARK DIAGNOSTICS, INC.

AMENDMENT OF RESTRICTED STOCK, RESTRICTED STOCK UNIT AND/OR STOCK OPTION AGREEMENT(S)

THIS AMENDMENT OF RESTRICTED STOCK, RESTRICTED STOCK UNIT AND/OR STOCK OPTION AGREEMENT(S) (this " ***Amendment*** ") is made by and between GenMark Diagnostics, Inc., a Delaware corporation (the " ***Company*** "), and _____ (the " ***Participant*** ").

RECITALS

WHEREAS, the Company has previously granted the Participant certain equity awards as set forth on Attachment A hereto and may (but need not) grant additional equity awards to the Participant following the Effective Date identified in Section 1 below (collectively, the " ***Awards*** "), which may consist of Restricted Stock, Restricted Stock Units and/or Options granted pursuant to the Company's 2010 Equity Incentive Plan (as amended, the " ***Plan*** "); and

WHEREAS, the Company and the Participant wish to amend the applicable agreements governing such Awards (collectively, the " ***Award Agreements*** ") to provide for acceleration of vesting of such Awards pursuant to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, the Company and the Participant agree as follows:

1. Effective Date . This Amendment is effective as of May __, 2016 (the " ***Effective Date*** ").

2. Definitions . Unless otherwise defined herein, capitalized terms shall have the meanings assigned to such terms in the applicable Award Agreement and the Plan.

3. Acceleration of Vesting of Restricted Stock Awards . With respect to the Restricted Stock Award(s), if any, indicated on Attachment A, and with respect to any Restricted Stock Award(s) granted to the Participant by the Company's Board of Directors or Compensation Committee thereof (as applicable, the " ***Administrator*** ") under the 2010 Plan after the Effective Date (if any), upon a Change in Control, one hundred percent (100%) of the shares subject to such Award(s) shall automatically become vested and non-forfeitable as of the date of the Change in Control.

4. Acceleration of Vesting of Option and Restricted Stock Unit Awards . With respect to the Options and Restricted Stock Units, if any, indicated on Attachment A, and with respect to any Options and/or Restricted Stock Units granted to the Participant by the Administrator under the 2010 Plan after the Effective Date (if any), upon a Change of Control, one hundred percent (100%) of the shares subject to such outstanding Award(s) which were not otherwise Vested Shares or Vested Units, as applicable, shall automatically become Vested Shares or Vested Units, as applicable, as of the date of such Change of Control.

5. Continuation of Other Terms . Except as set forth herein, all other terms and conditions of the Award Agreement(s) shall remain in full force and effect.

6. Tax Consequences . The Participant acknowledges that the Company makes no representation or warranty regarding the tax consequences of this Amendment. The Participant has been apprised that if the vesting of such Options were to be accelerated, the Options' tax status may, to the extent any such Option was designated as an Incentive Stock Option, be converted in whole or in part into a Nonstatutory Stock Option. In addition, the effect of accelerating the vesting of the Restricted Stock Awards and/or Restricted Stock Units may also result in the acceleration

of the year in which such shares would otherwise be taxable to the Participant. **The Participant should consult with the Participant's own tax, legal and financial advisors regarding the consequences of this Amendment.**

7. Applicable Law. This Amendment shall be governed by the laws of the State of California as such laws are applied to agreements between California residents entered into and to be performed entirely within the State of California.

GenMark Diagnostics, Inc.

Date: _____, 2016 By: _____
Hany Massarany
President & Chief Executive Officer

Participant:

Date: _____, 2016 _____
[Name of Participant]

Attachment A

RESTRICTED STOCK AWARD(S)

Date of Grant	Number of Shares Originally Subject to Award(s)

RESTRICTED STOCK UNIT(S)

Date of Grant	Number of Shares Originally Subject to Award(s)

STOCK OPTION AWARD(S)

Date of Grant	Number of Shares Originally Subject to Award(s)	Exercise Price

Exhibit 10.31

October 12, 2012

Eric Stier
[Address]

Dear Eric:

Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics ("GenMark Dx") is pleased to offer you employment in the position of **VP, Legal Affairs** reporting to GenMark's Chief Financial Officer, with a start date of **November 5, 2012** . Subject to your performance as well as Company requirements, you will be considered for the position of General Counsel & Corporate Secretary reporting to GenMark's Chief Executive Officer within 18 months of your start date.

Your annual gross salary will be **$195,000** 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 **30% of your base salary** .

The Company will also provide you with a signing bonus of **$30,000** payable as soon as practicable following your start date. In the event you terminate voluntarily from the company within 1 year of employment, GenMark may seek prorated reimbursement of your signing bonus.

We are also pleased to inform you that the Company will recommend for you to be granted the equivalent value of **30,000 GenMark Diagnostics, Inc. Stock Options** - to be awarded via a combination of stock options and restricted common stock - subject to blackout windows and board approval at the next board meeting following your start date. The Company will also recommend for you to be granted the equivalent value of **15,000 GenMark Stock Options** - to be awarded via a combination of stock options and restricted common stock - subject to blackout windows and board approval at the March, 2013 board meeting. The shares will be granted at the closing price on the date of grant. The Stock Option vesting schedule would be a 25% cliff vest at the one year anniversary of the date of grant and the remaining 75% in equal monthly installments for three years thereafter. The Restricted Common Stock 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. You will also be eligible for accelerated vesting upon a Change in Control, per GenMark Dx's "Amendment of Stock Option Agreement."

Additionally, you will be provided a severance provision of six months' base salary continuation, including health care and benefits coverage, in the event you are terminated by GenMark Dx for any reason other than Cause, within 18 months following your start date. The severance is contingent upon the usual and customary release of claims.
Stier Offer

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 pay, 10 sick days, holiday pay, life insurance, health insurance, disability insurance 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 Non-Disclosure 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 Non-Disclosure Agreement to formally accept this offer of employment. This offer will expire on **Sunday October 14, 2012** 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 transformation!

Sincerely,
/s/Jennifer Williams

Jennifer Williams
SVP Global Operations & Human Resources

By accepting, I agree to all terms of this offer and the Confidentiality and Non-Disclosure Agreement.

/s/ Eric Stier 10/13/2012
Eric Stier Date

Exhibit 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

(1) Registration Statement (Form S-3 No. 333-187371) of GenMark Diagnostics, Inc.,
(2) Registration Statement (Form S-8 No. 333-189348) pertaining to the 2013 Employee Stock Purchase Plan of GenMark Diagnostics, Inc.,
(3) Registration Statement (Form S-8 Nos. 333-194514, 333-187393, 333-182268, and 333-168892) pertaining to the 2010 Equity Incentive Plan of GenMark Diagnostics, Inc., and
(4) 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 February 28, 2017 , 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, 2016 .

/s/ Ernst & Young LLP

San Diego, California
February 28, 2017

Exhibit 31.1

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

I, Hany Massarany, 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: 2/28/2017

By: /s/ Hany Massarany

Hany Massarany

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, 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: 2/28/2017

By: /s/ Scott Mendel

Scott Mendel

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, 2016 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Hany Massarany, 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: 2/28/2017

By: /s/ Hany Massarany
Hany Massarany
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, 2016 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Scott Mendel, 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: 2/28/2017

By: /s/ Scott Mendel
Scott Mendel
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.