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

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**FORM 10-K**

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(Mark One)

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

For the year ended December 31, 2015

**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

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

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**27-2053069**  
(I.R.S. Employer Identification No.)

**5964 La Place Court, Carlsbad, California**  
(Address of principal executive offices)

**92008-8829**  
(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:  
**Common Stock, par value \$0.0001 per share**

Name of Each Exchange on which Registered:  
**The NASDAQ Stock Market LLC  
(NASDAQ Global Market)**

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

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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

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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, 2015, 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 \$364,778,000 based on the closing sale price for the registrant's common stock on the NASDAQ Global Market on that date of \$9.06 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 19, 2016 was 42,757,475. The common stock is listed on the NASDAQ Global Market (trading symbol "GNMK").

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**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 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<sup>®</sup>, eSensor<sup>®</sup>, XT-8<sup>™</sup> and ePlex<sup>™</sup> 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 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 our proprietary eSensor® detection technology. References herein to “we,” “us” or “our” refer to GenMark Diagnostics, Inc. and its wholly owned subsidiaries, unless the context specifically requires otherwise.

#### Overview

Our proprietary eSensor electrochemical technology enables fast, accurate and highly sensitive detection of multiple distinct biomarkers in a single sample. We are currently focused on developing and commercializing eSensor-based instruments and diagnostic tests for performing highly multiplexed reactions to simultaneously detect numerous, clinically relevant pathogens and/or genetic markers in rapidly expanding market segments. We currently sell our XT-8 instrument and related diagnostic and research tests, which collectively we refer to as our XT-8 system, in the United States. In addition, we have developed and intend to commercially launch our sample-to-answer ePlex instrument and its associated diagnostic tests, which we collectively refer to as our ePlex system, in Europe and the United States during 2016. All of our product revenues for 2015 were derived from sales of our XT-8 system.

Our XT-8 system received 510(k) clearance from the United States Food and Drug Administration, or FDA, and is designed to support a broad range of molecular diagnostic and research tests with a compact and easy-to-use workstation and disposable test cartridges. Our XT-8 system supports up to 24 independent test cartridges, each of which can be run independently, resulting in a highly convenient and flexible workflow for our XT-8 customers, which are primarily hospitals and reference laboratories. As of December 31, 2015, we had an installed base of 633 XT-8 analyzers, or placements, with our customers. We have a menu of eight tests for use with our XT-8 instrument. Four diagnostic tests which run on our XT-8 instrument have received FDA clearance: our Respiratory Viral Panel; our Cystic Fibrosis Genotyping Test; our Warfarin Sensitivity Test; and our Thrombophilia Risk Test. We have also developed a number of hepatitis C virus, or HCV, genotyping tests and custom manufactured reagents, as well as other research-based and pharmacogenomics products, versions of which are available for use with our XT-8 instrument for research use only (RUO).

In addition, we have developed our sample-to-answer ePlex instrument, 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 impaired 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 have initiated development programs for seven assays for our ePlex instrument, which include a respiratory panel (RP), gram-positive (GP) and gram-negative (GN) blood culture identification panels, a gastrointestinal (GI) pathogen panel, an HCV genotyping test (HCVg), a central nervous system (CNS) panel, and a fungal panel (FP). We intend to continue investing in our ePlex system and its related test menu for the foreseeable future.

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, 2015 and 2014 were approximately \$42.2 million and \$38.3 million, respectively. As of December 31, 2015, we had an accumulated deficit of \$304.7 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 Strategy

Our goal is to become the market leading provider of automated, multiplex molecular diagnostic testing systems. We intend to commercially launch our ePlex system in Europe and the United States during 2016, as well as expand the use of our XT-8 system in the United States. In order to achieve these objectives, we intend to:

- **Launch our ePlex System.** We believe the ePlex system will be attractive to a broader 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. We have initiated the development of seven assays for our ePlex system and anticipate continuing to invest in expanding our assay test menu for the foreseeable future.
- **Grow our Installed Base of Customers.** We have identified those laboratories and hospitals that we believe will benefit from our eSensor technology. We intend to leverage our commercial organization to commercially launch and drive placements of our ePlex system both domestically and internationally, as well as place additional XT-8 systems in the United States. 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 accredited physician education programs and seminars, product training for our customers and reimbursement support. These activities are designed to aid in establishing the clinical 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 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 proprietary technology and processes, we attach our capture probes to a proprietary monolayer on the surface of a gold electrode within our proprietary 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 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 DNA/RNA 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 signal 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 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 Test Cartridges.** Our XT-8 test cartridges are devices specifically configured for a particular diagnostic test to be used within our XT-8 instrument. Each test cartridge includes a sample compartment and a plastic cover that forms a hybridization chamber. The test cartridge is fitted with a diaphragm pump and valves that circulate the hybridization solution, including the signal probe and prepared patient sample, when inserted into the XT-8 instrument. The test cartridge also includes a printed circuit board consisting of an array of gold-plated electrodes, a silver/silver chloride reference electrode, and two auxiliary electrodes. Each electrode is customized with a proprietary monolayer that immobilizes the DNA capture probes specific for each target of a test panel. The test cartridge also contains an electrically erasable, programmable read-only memory (EEPROM) component that stores information related to the cartridge such as an assay identifier, cartridge lot number and expiration date.

**Our XT-8 Instrument.** Our XT-8 instrument is a 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. Each module contains a test cartridge connector, a precision-controlled heater, an air pump and electronics. The air pumps drive the diaphragm pump and valve system in the test cartridge, eliminating fluid contact between the module and the cartridge. The pneumatic pumping enables recirculation of the hybridization solution allowing the target DNA and the signal probes to efficiently hybridize with the complementary capture probes on the electrodes. The diaphragm pump in the test cartridge is connected to a pneumatic source from the XT-8 instrument and provides unidirectional pumping of the hybridization mixture through the cartridge during hybridization.

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

<b><u>Key Features &amp; Benefits</u></b>	<b><u>Description</u></b>
Broad Test Menu	Eight tests available on our XT-8 instrument including 4 FDA cleared assays across a number of areas in molecular diagnostics.
Fast Turnaround	Approximately 30 minutes to result from 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 Sample-To-Answer Test Cartridges.** Our ePlex test cartridges are single use, fully-integrated consumables containing all necessary reagents for a particular diagnostic test to be used within our ePlex instrument. Each test cartridge includes a sample compartment with a plastic cover into which a raw or minimally prepared sample is placed. The test cartridge contains liquid reagents in proprietary blister packs, optimized for long-term reagent storage and delivery into the appropriate reagent reservoirs. The test cartridge also contains biologic reagents such as enzymes and oligonucleotides, stabilized with proprietary additives designed to support long-term room temperature stability and dried onto various internal surfaces where they can be rehydrated for use during the sample-to-answer diagnostic test. The ePlex test cartridge also includes a printed

circuit board consisting of an array of gold-plated electrodes. Using the same eSensor technology contained in XT-8 cartridges, each electrode is similarly customized with a proprietary monolayer that immobilizes the DNA capture probes specific for each target of a test panel. The ePlex test cartridge also contains an EEPROM that stores information related to the cartridge such as an assay identifier, cartridge lot number and expiration date. The ePlex EEPROM and associated workflow and programming also supports positive patient identification, helping to ensure error-free linking of the ePlex test report to the correct patient.

**Our ePlex Instrument.** Our ePlex instrument is a multiplex platform that has a modular design consisting of an integrated touch screen and up to four analyzers. Each analyzer contains six modules into which individual ePlex sample-to-answer test cartridges are placed. The test cartridge modules operate independently supporting continuous random access of up to 24 independent test cartridges. Each module contains a test cartridge connector, several precision-controlled heaters, a mix motor, an air pump and mechanisms for dispensing liquid from blister packs and positioning a small magnet. Each module also contains all of the necessary electronics hardware and firmware for controlling the module, performing real-time monitoring, calibration testing and generating test results. The air pump, blister/magnet mechanisms and motor drive the nucleic acid extraction and reagent dispensing initial phase of the sample-to-answer diagnostic tests and avoid fluid contact between the ePlex module and the cartridge. All subsequent steps are driven by a proprietary electrowetting technology which we have exclusively licensed within a defined field of use.

We believe our ePlex system will offer reference laboratories and hospitals the following benefits:

<b><u>Key Features &amp; Benefits</u></b>	<b><u>Description</u></b>
Broad Test Menu	Seven tests are in development on our ePlex instrument.
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. The test cartridge is self-contained, with all required reagents stored in room-temperature stable formats.
Fast Turnaround	Results are expected to be produced in approximately 60-90 minutes 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.

## **Market Opportunity**

We believe the global market for molecular diagnostics is currently approximately \$5.0 billion and will experience a growth rate of over 10% per year over the course of the next several years based on research published by leading market research firms. Although we believe the global market for molecular diagnostics is approximately \$5.0 billion, we believe the aggregate global market for the tests we currently offer, are actively developing on ePlex, or will consider developing in the near-term is approximately \$2.3 billion and is expected to grow by more than 20% per year for the next several years. Many factors are driving growth of this market, including increased demand for infectious disease diagnostics panels, the expansion of genetic testing for disease predisposition, and advances in personalized medicine, such as the tailoring of therapies to those individuals most likely to respond.

## **Research and Development**

In addition to developing our ePlex system and expanding our diagnostic test menus, our research and development team is focused on the following initiatives:

- **On Market Product Support.** A role of our research and development team is to assist our manufacturing and quality assurance teams in ensuring high product quality and thorough complaint handling and investigation. In addition, we work to improve 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 research and development organization also helps establish 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 and ancillary reagents in Carlsbad, California. 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. We also outsource the manufacture of our ePlex instrument. We rely on third party suppliers, including in certain instances, sole source suppliers, for oligonucleotide and other raw materials used in our products and much of the disposable component molding and sub-component assembly for our test cartridges.

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 also have controlled 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 anticipated commercialization of our ePlex system in Europe and the United States in 2016, while also continuing to expand 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 intend to utilize a direct sales and technical support team to sell our ePlex system in certain key European countries, which we expect will be augmented by marketing partners and distributors in other geographies as we further expand 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 our expanding molecular test menu, 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 XT-8 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 a customer commitment to purchase a minimum number of test cartridges over the term of the agreement, and a portion of the charge for each cartridge equates to a usage fee for the instrument. Our reagent rental agreements do not typically provide for any cancellation rights by the customer.

## **Customers**

In 2015, Laboratory Corporation of America, Inc. represented 17% of our total revenue. In 2014, no single customer represented more than 10% of our total revenue. In 2013, Natural Molecular Testing Corporation, or NMTC, represented approximately 30% of our total revenue.

Instrument placements are defined in terms of the number of analyzers sold to or placed with a customer, reflecting a direct correlation between the reagent test revenue opportunity and the number of test cartridges that can be analyzed at any one time. As of December 31, 2015, we had placed 633 XT-8 analyzers with our customers, as compared to 540 analyzer placements at December 31, 2014. The increase in analyzers placed and related revenue generated in 2015 over the prior year is due to an increase in the number of new customers buying our products and growth in the sale of consumables to existing customers.

## **Competition**

We primarily face competition in the molecular diagnostic testing markets with testing products and systems developed by public and private companies such as Cepheid, Siemens, Hologic, Inc., Luminex Corporation, Nanosphere, Inc., Seegene, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd., bioMerieux (which acquired Biofire Diagnostics, Inc.) and Abbott Molecular Diagnostics, a division of Abbott Laboratories. 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 and 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 currently exclusively license the digital microfluidics technology utilized in our ePlex system within a defined field of use.

We believe that our patent portfolio, which includes approximately 120 owned and exclusively licensed U.S. and foreign patents and approximately 35 pending applications, provides us with robust protection of our electrochemical detection techniques, chemical insulators and attachment points on electrode surfaces and other technology that, collectively, form the basis of our eSensor platform. We continue to pursue the issuance of new patents to protect our ongoing research, development and commercial activities, including 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 and pending trademark registrations in the United States and Europe include eSensor®, word and design marks for GenMark®, GenMark DX®, eSensor®, XT-8™, eSensor XT-8™, ePlex™, and GenMark ePlex™, among others.

Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed but renewable terms.

## **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.

***Proposed Regulation of Laboratory Developed Tests (LDTs).*** In October 2014, the FDA promulgated draft guidance which describes a new proposed regulatory framework for LDTs. Based on this proposal, clinical laboratories that develop and use LDTs would be required to comply with specific regulatory requirements (e.g., adverse event reporting, quality system regulation, 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 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 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 two years. 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 began paying the tax in January 2013 and continued 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, 2015, we had 233 employees. Approximately 114 employees were involved in research and development, 47 in operations, manufacturing and quality assurance, 44 in sales and marketing, and 28 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 principal corporate offices are located at 5964 La Place Court, Carlsbad, California. We also lease additional manufacturing space in Carlsbad, California, which is located nearby our corporate offices.

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](http://www.genmarkdx.com). Our SEC reports and other financial information can be accessed through the investor relations section of our website. Some of the information found on our website is not part of this or any other report we file with or furnish to the SEC.

### Item 1A. RISK FACTORS

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

#### ***We may not successfully commercialize our ePlex system and its related test menu.***

Our current plan for achieving positive cash flow and our future growth projections relies upon the successful development and commercialization of our ePlex system and its related test menu. We have designed our ePlex system to integrate automated nucleic acid extraction and amplification with our eSensor technology to allow operators to place raw or minimally prepared patient samples directly into our test cartridges and obtain clinically relevant results. Based on extensive market research and input received from our customers, we believe that our ePlex system will offer advantages over competitive systems, including superior multiplexing capability, reduced hands-on processing time, testing capacity and flexibility, and other factors. However, the commercial success of ePlex will depend on a number of factors, including, but not limited to, our ability to manage the risks associated with technology and manufacturing process transfer and scaling up new product production, our and our supplier's ability to consistently manufacture high quality products, timely market introduction, product reliability, overall market acceptance, our ability to offer a broad test menu at a competitive price, the effective management of purchase and supply commitments and inventory levels in line with anticipated product demand, the availability of products in appropriate quantities and at expected costs to meet anticipated demand and drive market adoption, increased repair or re-engineering costs due to product returns or design adjustments, and the risk that new products may not have the level of quality in the early stages of introduction that our customers expect. If we are unsuccessful in effectively commercializing our ePlex system within our expected time frame, or at all, we may invest in anticipation of growth that does not materialize, or which develops more slowly than we expect, which in turn could harm our financial results, reduce our cash balances, result in overcapacity, and our business and future prospects may be adversely affected.

#### ***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, 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 may be unsuccessful in expanding sales of our product offerings outside the United States.***

Assuming we receive the applicable regulatory clearances or approvals, we plan to offer our molecular diagnostic products in European and other international markets in the near future. We intend to utilize a direct sales and technical support team in certain key European countries, which we expect will be augmented by a third party logistics provider that will be responsible for managing the international delivery of our products and providing certain other related services. We intend to also utilize marketing partners and distributors in certain locations as we expand internationally. We have introduced our XT-8 system to key opinion leader sites in certain European countries in order to familiarize these markets with our technology and certain tests in advance of their anticipated European launch of our ePlex system. If we are unable to establish the infrastructure or recruit highly qualified personnel to support our 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 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.

In order to market our products in the European Union and many other foreign jurisdictions, we, or our distributors or partners, may be required to meet and/or comply with numerous and varying regulatory requirements before selling our products in such jurisdictions. The applicable approval or clearance procedures may vary among countries and could involve additional testing or other requirements. We, our distributors or other partners may not obtain applicable approvals or clearances from regulatory authorities outside the United States on a timely basis, if at all, which could harm our ability to expand into markets outside the United States.

***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.; bioMerieux, which acquired BioFire Diagnostics, Inc.; Qiagen NV; Abbott Molecular Diagnostics, a division of Abbott Laboratories; Hologic, Inc. and Cepheid;
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods, including Quest Diagnostics Incorporated and Laboratory Corporation of America; and
- companies that manufacture laboratory-based tests and analyzers, including: Cepheid; Siemens; Hologic, Inc.; Qiagen NV; bioMérieux; Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd.; and Abbott Molecular Diagnostics.

Our diagnostic tests also face competition from laboratory developed tests, or 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.

***We and our key suppliers may have difficulties scaling manufacturing operations for our anticipated future 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 newly developed, unique products is a complex process. We or our suppliers may not be able to consistently produce sufficient quantities of high quality products. If we or our key suppliers encounter difficulties in scaling manufacturing operations as a result of, among other things, process transfer complexities, quality control and quality assurance issues, and availability of components, equipment and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results within the time frame we expect, or at all. In addition, finding solutions to product quality and reliability issues can be time consuming and expensive, and we may incur significant costs or lose revenue as a result of, among other things, delayed product introduction, product recalls, shipment holds, and warranty and service obligations.

To manage our anticipated future growth effectively, we must enhance our manufacturing and supply chain capabilities 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 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 quality from our single source suppliers, could result in delays or difficulties successfully launching 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 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 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.

***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 17% of our total revenue for the fiscal year ended December 31, 2015. The loss of a significant customer or a significant reduction in the amount of product ordered by our significant customer 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 system;
- 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 XT-8 system and its related test menu and our expected commercialization of ePlex, 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 with General Electric Capital Corporation, or GECC, and certain other lenders, which was amended in September 2015. Pursuant to the agreement, we borrowed \$10 million in March 2015 and may borrow up to an additional \$25 million if we timely satisfy certain regulatory requirements related to 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 the identified regulatory milestones related to our ePlex system, we may not have the ability to borrow certain 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 \$42.2 million and \$38.3 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015, we had an accumulated deficit of \$304.7 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.

***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 facility. We outsource manufacturing of our XT-8 system and much of the disposable component molding for our test cartridges. In 2012, we formalized our relationship with Leica the contract manufacturer of our XT-8 instrument. Leica specializes in manufacturing of electronic and electromechanical devices for medical use. While we work closely with Leica to ensure continuity of supply while maintaining high quality and reliability, we cannot guarantee that these efforts will be successful. We intend to manufacture the proprietary test cartridges for our ePlex system, and we outsource the manufacture of our ePlex system to a third party manufacturing partner.

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.

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

We are investing significantly in the development of our ePlex instrument and its related molecular diagnostic tests to expand our future product offerings. Our molecular diagnostic products, including our ePlex system, will require 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States. For international commercialization, the classification of, and the regulatory pre-market requirements for, our molecular diagnostic products vary from country to country. There are a number of potential risks associated with the regulatory review processes for our products in development. For example, regulatory authorities may require that we conduct additional studies that could impact the cost associated with product development and could potentially delay commercial launch of the product. In addition, we may be unsuccessful in obtaining regulatory clearance for all of our desired intended uses for our products or product approval or clearance within certain jurisdictions.

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, including our ePlex instrument and products that are currently in design or development, 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.

***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 federal False Claims Act, or 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, 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.

Once we commence commercial operations outside the United States, we will be 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 two years. 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 began paying the tax in 2013 and continued through 2015. 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. 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 approximately 120 owned and exclusively licensed patents and approximately 35 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. A recall involving our XT-8 system or our diagnostic tests would be particularly harmful to our business and financial results.

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 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. We intend to continue to dedicate a significant portion of our resources to the commercialization of our XT-8 system and its related test menu, while also dedicating significant resources to the commercialization of our ePlex system and the development of its related test menu. 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.***

The majority of our XT-8 systems are provided to customers via "reagent rental" agreements, under which customers are afforded the right to use the XT-8 system 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 XT-8 systems 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 XT-8 systems. 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, 2015, we had net operating loss, or NOL, carryforwards available of approximately \$166.4 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2034. 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 non-U.S. NOL carryforwards as of December 31, 2015. 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 a facility 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 an additional 22,000 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 intend to utilize primarily for future manufacturing operations. 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**

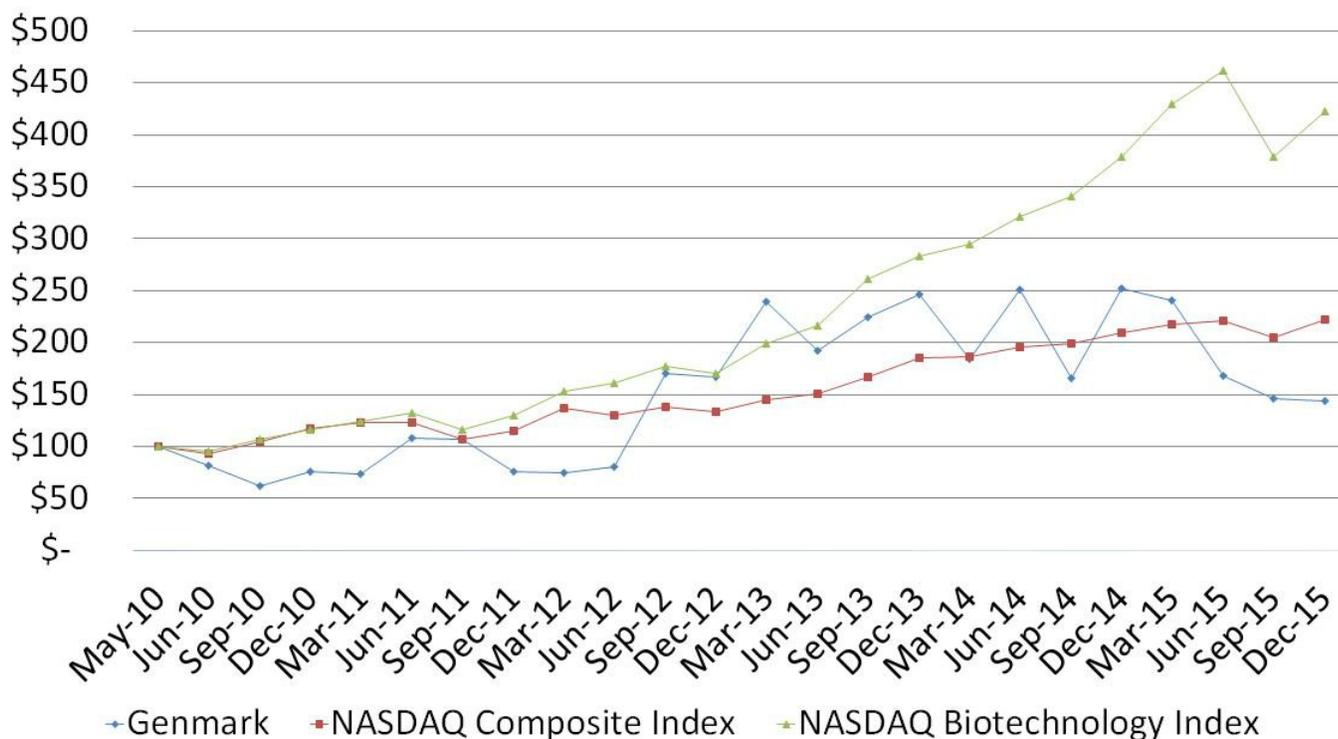
Our common stock has been quoted on The NASDAQ Global Market under the symbol “GNMK” since May 28, 2010. Prior to that time, our stock traded under the ticker symbol “OMH” on the London Stock Exchange. The following table sets forth for the indicated periods the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market.

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2015</b>		
First Quarter	\$ 14.40	\$ 11.67
Second Quarter	\$ 13.04	\$ 8.81
Third Quarter	\$ 10.55	\$ 7.22
Fourth Quarter	\$ 9.74	\$ 4.63
<b>Year Ended December 31, 2014</b>		
First Quarter	\$ 14.18	\$ 9.28
Second Quarter	\$ 13.63	\$ 8.48
Third Quarter	\$ 13.87	\$ 8.64
Fourth Quarter	\$ 14.18	\$ 8.62

**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.

**Compare Cumulative Total Returns Among GenMark,  
NASDAQ Composite Index, and NASDAQ Biotechnology  
Index**



**Stockholders**

The last reported sale price of common stock on February 19, 2016 as reported on the NASDAQ Global Market was \$4.65. As of February 19, 2016, there were 2,844 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 loan agreement with GECC contains a negative covenant which may limit our ability to pay dividends. We currently intend to retain any future earnings to fund the operation, development and expansion of our business. Any future determination to pay dividends will be at the sole discretion of our Board of Directors and will depend upon a number of factors, including our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in our current and future debt arrangements, and other factors our Board of Directors may deem relevant.

**Item 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The following selected consolidated financial data relates to GenMark Diagnostics, Inc. and its consolidated subsidiaries. The selected consolidated statement of comprehensive loss data presented below of GenMark Diagnostics, Inc. for the years ended December 31, 2015, 2014, and 2013 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2015, and 2014 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, 2012 and 2011 and the selected consolidated balance sheet data as of December 31, 2013, 2012, and 2011 have been derived from the 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,				
	2015	2014	2013	2012	2011
<b>Consolidated Statements of Comprehensive Loss Data:</b>					
(In thousands, except per share data)					
<b>Revenue</b>					
Product revenue	\$ 39,029	\$ 30,328	\$ 27,204	\$ 20,211	\$ 4,700
License and other revenue	382	266	200	258	309
<b>Total revenue</b>	<b>39,411</b>	<b>30,594</b>	<b>27,404</b>	<b>20,469</b>	<b>5,009</b>
Cost of revenue	15,317	13,127	15,570	11,640	6,206
<b>Gross profit (loss)</b>	<b>24,094</b>	<b>17,467</b>	<b>11,834</b>	<b>8,829</b>	<b>(1,197)</b>
<b>Operating expenses</b>					
Sales and marketing	14,385	12,629	12,818	6,378	4,969
General and administrative	13,772	12,069	11,836	10,806	8,960
Research and development	37,472	31,823	22,060	13,536	8,737
<b>Total operating expenses</b>	<b>65,629</b>	<b>56,521</b>	<b>46,714</b>	<b>30,720</b>	<b>22,666</b>
<b>Loss from operations</b>	<b>(41,535)</b>	<b>(39,054)</b>	<b>(34,880)</b>	<b>(21,891)</b>	<b>(23,863)</b>
<b>Other income (expense):</b>					
Interest income (expense), net	(755)	224	384	(48)	(74)
Other income (expense)	133	(6)	897	(16)	19
<b>Total other income (expense)</b>	<b>(622)</b>	<b>218</b>	<b>1,281</b>	<b>(64)</b>	<b>(55)</b>
<b>Loss before income taxes</b>	<b>(42,157)</b>	<b>(38,836)</b>	<b>(33,599)</b>	<b>(21,955)</b>	<b>(23,918)</b>
Income tax expense (benefit)	40	(573)	44	148	52
<b>Net loss</b>	<b>\$ (42,197)</b>	<b>\$ (38,263)</b>	<b>\$ (33,643)</b>	<b>\$ (22,103)</b>	<b>\$ (23,970)</b>
Net loss per share, basic and diluted	<b>\$ (1.00)</b>	<b>\$ (0.93)</b>	<b>\$ (0.95)</b>	<b>\$ (0.84)</b>	<b>\$ (1.45)</b>
Weighted average number of shares outstanding, basic and diluted	42,157	41,346	35,253	26,215	16,572
<b>As of December 31,</b>					
	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
(In thousands)					
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents and marketable securities(1)(2)(3)	\$ 45,465	\$ 70,506	\$ 105,589	\$ 51,250	\$ 30,320
Total assets	70,667	91,970	121,754	68,016	38,186
Long-term liabilities	11,481	1,653	2,349	2,392	1,171
Total liabilities	22,070	13,946	12,586	11,566	7,552
Accumulated deficit	(304,669)	(262,472)	(224,209)	(190,566)	(168,463)
Total stockholders’ equity (1)(2)(3)	48,597	78,024	109,168	56,450	30,634

(1) 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.

- (2) 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.
- (3) In June 2011, we issued approximately 8.1 million shares of common stock at a price of \$4.25 per share. We raised approximately \$31.7 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 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. 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 wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term incentive awards and all warrants issued by Osmetech were exchanged for options and warrants exercisable for the common stock of the 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.

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor<sup>®</sup> detection technology. Our proprietary eSensor electrochemical technology enables fast, accurate and highly sensitive detection of multiple distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the FDA and is designed to support a broad range of molecular diagnostic and research tests with a compact and easy-to-use workstation and disposable test cartridges. Our XT-8 system supports up to 24 independent test cartridges, each of which can be run independently, resulting in a highly convenient and flexible workflow for our XT-8 customers, which are primarily hospitals and reference laboratories. As of December 31, 2015, we had an installed base of 633 XT-8 analyzers, or placements, with our customers.

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, 2015, 2014, and 2013 were approximately \$42.2 million, \$38.3 million, and \$33.6 million, respectively. As of December 31, 2015, we had an accumulated deficit of \$304.7 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 have a menu of eight tests for use with our XT-8 instrument. Four diagnostic tests which run on our XT-8 instrument have received FDA clearance: our Respiratory Viral Panel; our Cystic Fibrosis Genotyping Test; our Warfarin Sensitivity Test; and our Thrombophilia Risk Test. We have also developed a number of HCV genotyping tests and custom manufactured reagents, as well as other research-based and pharmacogenomics products, versions of which are available for use with our XT-8 instrument for research use only (RUO).

In addition, we have developed our sample-to-answer ePlex system, which integrates automated nucleic acid extraction and amplification with our eSensor detection technology to enable operators using the ePlex system 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 impaired 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 have initiated development programs for seven assays for our ePlex system, which include a respiratory panel (RP), gram-positive (GP) and gram-negative (GN) blood culture identification panels, a gastrointestinal (GI) pathogen panel, an HCV genotyping test (HCVg), a central nervous system (CNS) panel, and a fungal panel (FP). We intend to continue investing in our ePlex system and its related test menu for the foreseeable future.

### ***Revenue***

Revenue from operations includes product sales, principally of our diagnostic tests for use with our XT-8 instrument. We primarily place our XT-8 instrument 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 XT-8 instrument for sale.

Revenue also includes licensing revenue from the out-licensing of our electrochemical detection technology. We may enter into additional sub-licenses of our technology generating additional revenue, but do not anticipate that this will provide a significant portion of our future revenue.

### ***Cost of Revenues***

Cost of revenues includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacturing of our consumable test kits for our XT-8 system, including royalties on product sales. Cost of revenues also includes depreciation on revenue generating systems that have been placed with our customers under a reagent rental agreement, cost of systems sold to customers, amortization of licenses related to our products and other costs such as warranty, royalty and customer technical support. We manufacture our test cartridges in our facility and have recently invested in significant capacity for expansion. This 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 XT-8 instruments are procured from a contract manufacturer and are generally capitalized as fixed assets and depreciated on a straight line basis over their useful life as a charge to cost of revenues. We expect our cost of revenues to increase as we place additional XT-8 instruments and manufacture and sell an increasing menu of accompanying diagnostic tests; however, we expect our gross margins related to our XT-8 instruments to increase as manufacturing efficiencies, improved procurement practices, instrument reliability increases, and other improvements decrease costs as a percentage of revenues.

### ***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 shows. We expect sales and marketing costs to increase as we scale-up our domestic and international commercial efforts to expand our customer base.

### ***Research and Development Expenses***

Research and development expenses primarily include expenses related to the development of our ePlex instrument and related 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 consisted of salaries, benefits, stock-based compensation costs, outside design and consulting services, laboratory supplies, contract research organization expenses, clinical study supplies, 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, travel, insurance, and public company expenses, such as stock transfer agent fees and listing fees for NASDAQ. For the year ended December 2013, an impairment charge of \$1.6 million related to previously capitalized license payments was included in general and administrative expenses as a result of the termination of a license agreement.

### ***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. Prior to our initial public offering in 2010, exchange gains and losses included those arising on cash balances held by Osmetech denominated in currencies other than its functional currency, the British Pound. Since the initial public offering, the functional currency of GenMark has been the U.S. dollar. In connection with the liquidation of Osmetech plc in the fourth quarter of 2013, we realized a translation loss of \$450,000 to eliminate accumulated other comprehensive loss.

### ***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.

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 of the instrument 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. 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.

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.

### ***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 to the 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, 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. We generally capitalize our XT-8 instruments, and provide these to customers for no charge. 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	5 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 2015 and 2014, we disposed of certain assets no longer in use with a net book value of \$153,000 and \$102,000, respectively, recorded to cost of revenue, sales and marketing, research and development, and general and administrative expenses based on the assets respective use. During 2013, we recorded a one-time impairment charge of \$302,000 related to production equipment which had been built for a former customer.

### ***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. During the year ended December 31, 2013, we recorded an impairment charge of \$1,624,000 related to previously capitalized payments made under a license agreement, which we terminated in December 2013.

### ***Stock-Based Compensation***

We grant stock options with an exercise price equal to the closing price of our common stock on the NASDAQ Global Market on each 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 is also estimated using the Black-Scholes option-pricing model and Monte Carlo Simulation Model. These models requires the use of highly subjective and complex assumptions which determine the fair value of stock-

based awards, including the stock option'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 volatility in our stock price expected over the expected term of the stock option.
- *Expected Dividend.* The Black-Scholes option-pricing model calls for 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 rate used in the Black-Scholes option-pricing model is based on published government rates in effect at the time of grant for periods corresponding with the expected term of the option.

### **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. Management is 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**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standard Board, or the FASB, or other standard setting bodies that we adopt as of the specified effective date. We believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

In April 2015, the FASB issued Accounting Standards Update (ASU) 2015-03, Interest - Imputation of Interest. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability. We have retrospectively adopted this standard. Our debt issuance costs have been recognized as a direct reduction to short-term and long-term debt liability in the condensed consolidated balance sheets for all periods presented.

In August 2015, the FASB issued Accounting Standards Update (ASU) 2015-14, Revenue from Contracts with Customers deferring the previously issued ASU 2014-09. This standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for us beginning in the first fiscal quarter of 2018 and allows for a full retrospective or a modified retrospective adoption approach. The new standard does not have a current impact on the unaudited consolidated financial statements presented. We are currently evaluating the impact of ASU 2014-09 on its consolidated financial statements.

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, "Balance Sheet Classification of Deferred Taxes", an update to ASC 740, Income Taxes (the "Update"). Current U.S. GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in the Update require that deferred tax liabilities and assets

be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in the Update. We chose to adopt the Update in fiscal year ended December 31, 2015 and apply this Update on a prospective basis.

**Comparison of Years Ended December 31, 2015, 2014 and 2013 (in thousands):**

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Revenue	\$ 39,411	\$ 30,594	\$ 27,404	\$ 8,817	29%	\$ 3,190	12%

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.

A former customer, Natural Molecular Testing Corporation, or NMTC, filed for bankruptcy during 2013. During the year ended December 31, 2013, revenue from NMTC was \$8,162,000. Our "base business" excludes revenues from this former customer.

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 purchases of our infectious disease assays and a 17% increase in the number of XT-8 analyzers installed at customer locations to 633 at December 31, 2015, from 540 as of December 31, 2014. Pricing changes did not have an impact on revenue during the current period.

For the year ended December 31, 2014, our base business grew 59%, or \$11,353,000, compared to the same period of 2013. Consumables revenue from our base business during the year ended December 31, 2014 increased by 71% to \$29,235,000 compared to \$17,123,000 in the prior year period. This increase in consumable revenue was primarily driven by increases in purchases of our infectious disease assays and a 31% increase in the number of XT-8 analyzers installed at customer locations to 540 at December 31, 2014, from 413 as of December 31, 2013. Pricing changes did not have an impact on revenue during the current period.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Cost of Revenue	\$ 15,317	\$ 13,127	\$ 15,570	\$ 2,190	17%	\$ (2,443)	(16)%
Gross Profit	\$ 24,094	\$ 17,467	\$ 11,834	\$ 6,627	38%	\$ 5,633	48 %

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 in the current year. Increases in our cost of revenue were attributable to product costs of \$2,548,000 corresponding to 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.

The decrease in cost of revenue for the twelve months ended December 31, 2014 compared to the twelve months ended December 31, 2013 was primarily related to the one-time inventory reserve expense recorded in 2013, of \$1,192,000 related to the NMTC bankruptcy, in addition to a \$748,000 decrease in personnel related costs and a \$404,000 decrease in amortization and depreciation expense. These decreases were partially offset by increased royalties expense of \$227,000. The improvement to gross profit during the year ended December 31, 2014, compared to December 31, 2013, was due to reduced excess and obsolete expense related to the NMTC bankruptcy, increased sales of higher margin products and a reduction in manufacturing personnel costs.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Sales and Marketing	\$ 14,385	\$ 12,629	\$ 12,818	\$ 1,756	14%	\$ (189)	(1)%

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 \$1,747,000 increase in salaries and employee related expenses, including

increased stock-based compensation expense of \$1,187,000, incurred in connection with expanding our domestic and international commercial organization.

The decrease in sales and marketing expense for the year ended December 31, 2014, compared to the year ended December 31, 2013, was primarily driven by a one-time charge to bad debt expense of \$2,702,000 related to amounts owed by NMTC which was recorded in 2013, which was offset by an increase in salaries and employee related expenses of \$2,187,000, including increased stock-based compensation expense of \$625,000, an increase in marketing communications and trade show expenses of \$323,000, and travel expenses of \$207,000, in each case incurred in connection with expanding our domestic and international organization.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
General and Administrative	\$ 13,772	\$ 12,069	\$ 11,836	\$ 1,703	14%	\$ 233	2%

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 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.

The increase in general and administrative expense for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily due to employee related expenses of \$1,377,000, including increased stock-based compensation expense of \$786,000, in addition to increased bank and payroll fees of \$221,000 and building lease and utilities expenditures of \$208,000, partially offset by a \$1,622,000 decrease in license expense resulting from a one-time impairment charge from the termination of a license agreement in 2013.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Research and Development	\$ 37,472	\$ 31,823	\$ 22,060	\$ 5,649	18%	\$ 9,763	44%

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 prototype materials to support our ePlex system and its related test menu.

The increase in research and development expense for the year ended December 31, 2014, compared to the year ended December 31, 2013, was primarily due to an increase in costs associated with the development of our ePlex instrument of \$6,109,000 and an increase in ePlex assay development costs of \$3,556,000, comprised largely of employee related expenses, outside services and prototype materials.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Other Income (Expense)	\$ (622)	\$ 218	\$ 1,281	\$ (840)	(385)%	\$ (1,063)	(83)%

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 preferred stock of Advanced Liquid Logic, Inc., or ALL, in the fourth quarter of 2014.

The change in other income (expense) for the year ended December 31, 2014, compared to the year ended December 31, 2013, was due primarily to the sale of our preferred stock investment in ALL in connection with ALL's acquisition by Illumina, Inc. resulting in a \$1,392,000 realized gain in 2013 and an increase in amortization of premiums on marketable securities of \$388,000, partially offset by the absence of the \$450,000 loss realized upon liquidation of our U.K. subsidiary Osmetech, which was recorded in the fourth quarter of 2013.

	Years ended December 31,			2015 vs 2014		2014 vs 2013	
	2015	2014	2013	\$ Change	% Change	\$ Change	% Change
Income Tax Expense (Benefit)	\$ 40	\$ (573)	\$ 44	\$ 613	107%	\$ (617)	(1,402)%

Due to net losses incurred, we have only recorded tax provisions associated with uncertain tax positions, interest on uncertain tax positions and minimum tax payments. The increase in income tax expense for the year ended December 31, 2015 was primarily due to the expiration of the statute of limitations on uncertain tax positions resulting in the recognition of a \$610,000 tax benefit recorded in 2014. The decrease in income tax expense for the year ended December 31, 2014 was primarily due to this same \$610,000 tax benefit recorded 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, 2015, we had \$45,368,000 of working capital, including \$45,465,000 in cash, cash equivalents, and marketable securities.

### Cash Flows

The following table shows cash flow information for the years ended December 31, 2015, 2014 and 2013:

	Years Ended December 31,		
	2015	2014	2013
Cash used in operating activities	\$ (31,915)	\$ (29,572)	\$ (23,796)
Cash provided by (used in) investing activities	19,321	29,417	(72,564)
Cash provided by financing activities	11,133	1,287	80,833
Effect of exchange rate changes on cash	(9)	—	—
Net increase (decrease) in cash and cash equivalents	\$ (1,470)	\$ 1,132	\$ (15,527)

### Cash flows used in operating activities

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 an additional \$3,067,000 cash outflow from changes in operating assets and liabilities, partially offset by \$4,658,000 in higher non-cash charges primarily comprised of stock-based compensation expense. The main drivers in the change in operating assets and liabilities included increases in inventory and a decrease in accrued compensation.

Net cash used in operating activities increased \$5,776,000 to \$29,572,000 for the year ended December 31, 2014, compared to \$23,796,000 for the year ended December 31, 2013. The increase in cash used in operating activities was primarily due to a \$4,620,000 increase in net loss and \$2,130,000 in lower non-cash charges primarily related to less bad debt expense and impairment, partially offset by \$974,000 less cash outflow from changes in operating assets and liabilities.

### Cash flows provided by (used in) investing activities

Net cash provided by investing activities 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 the ALL acquisition, partially offset by a decrease in purchases of marketable securities of \$5,408,000.

Net cash used in investing activities increased \$101,981,000 primarily due to \$54,500,000 increase from the maturity of short-term marketable securities and a decrease in purchases of marketable securities of \$48,136,000.

### Cash flows provided by financing activities

Net cash provided by financing increased \$9,846,000 to \$11,133,000 for the year ended December 31, 2015, 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.

Net cash provided by financing decreased \$79,546,000 to \$1,287,000 for the year ended December 31, 2014, primarily due to a decrease in proceeds from issuance of common stock related to the follow-on stock offering of \$85,735,000, partially offset by \$5,510,000 less in costs incurred in conjunction with the public offering.

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 U.S. and international commercial (sales and marketing) activities;
- the level of research and development investment required to and develop and commercialize our ePlex system and related test menu and maintain our XT-8 system;
- 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, the LSA, with GECC and certain other financial institutions, 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. In December 2015, GECC assigned its interest in the loan to Capital One Healthcare. Under the terms of the LSA, as amended, we may, subject to certain conditions, borrow:

- \$10,000,000 on or before March 31, 2015, which we borrowed in March 2015;
- an additional \$10,000,000, subject to our satisfaction of regulatory requirements necessary to CE Mark our ePlex system in Europe by a specified date;
- an additional \$15,000,000, 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.

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.

On September 30, 2015, the Company entered into an amendment to the LSA, pursuant to which the lenders internally reallocated certain funding commitments under the LSA between the lenders (but did not increase or reduce the aggregate amount of such commitments), and the parties adjusted certain of the Company's administrative financial reporting obligations and the dates by which certain future funding requirements must be satisfied.

#### ***Letter of Credit***

In September 2012, we provided a \$758,000 letter of credit issued by Banc of California to the landlord of our facility in Carlsbad, California. This letter of credit was secured with \$758,000 of restricted cash at September 30, 2015.

## Public Offering

On August 19, 2013, we completed the public offering of 8,765,000 shares of our common stock at a price of \$9.84 per share and raised approximately \$80,672,000 in net proceeds.

Although we do not currently anticipate requiring additional capital, if additional capital is required, we cannot be certain that it will be available when needed or that our actual cash requirements will not be greater than anticipated. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might 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, 2015, 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)	\$ 11,461	\$ 1,432	\$ 3,412	\$ 3,879	\$ 2,738
Licensing payment obligation	1,924	1,653	181	90	—
Instrument purchase obligations	29	29	—	—	—
Total obligations	<u>\$ 13,414</u>	<u>\$ 3,114</u>	<u>\$ 3,593</u>	<u>\$ 3,969</u>	<u>\$ 2,738</u>

- (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 February 2011, we entered into a 36-month operating lease for office equipment with total lease payments of \$85,000. In conjunction with the lease, the lessor paid us approximately \$27,000 to pay off previous contracts for similar equipment leased from a different vendor.

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 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.

In December 2015, we entered into a 60-month lease for computer server equipment with total lease payments of \$83,000.

## 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 facility, which is recorded as restricted cash on the 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, 2015, based on current interest rates and total borrowings 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**

All of our operating facilities are located within the United States. We are a U.S. entity and our functional currency is the U.S. dollar. All of our revenues were derived from sales in the United States. We have business transactions in foreign currencies, however, we believe we have no material 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, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for the years then ended. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended, 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, 2015, 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 23, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 23, 2016

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

	As of December 31,	
	2015	2014
<b>Current assets</b>		
Cash and cash equivalents	\$ 35,385	\$ 36,855
Marketable securities	10,080	33,651
Accounts receivable, net of allowances of \$2,727 and \$2,702, respectively	6,847	4,889
Inventories	3,054	2,137
Prepaid expenses and other current assets	591	575
<b>Total current assets</b>	<b>55,957</b>	<b>78,107</b>
<b>Non-current assets</b>		
Property and equipment, net	11,396	11,052
Intangible assets, net	2,376	1,870
Restricted cash	758	758
Other long-term assets	180	183
<b>Total assets</b>	<b>\$ 70,667</b>	<b>\$ 91,970</b>
<b>Current liabilities</b>		
Accounts payable	\$ 4,376	\$ 5,111
Accrued compensation	3,861	5,187
Other current liabilities	2,352	1,995
<b>Total current liabilities</b>	<b>10,589</b>	<b>12,293</b>
<b>Long-term liabilities</b>		
Deferred rent	1,257	1,445
Long-term debt	9,890	—
Other non-current liabilities	334	208
<b>Total liabilities</b>	<b>22,070</b>	<b>13,946</b>
<b>Commitments and contingencies—See note 7</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 42,551 and 41,859 shares issued and outstanding as of December 31, 2015 and December 31, 2014, respectively	4	4
Additional paid-in capital	353,233	340,502
Accumulated deficit	(304,669)	(262,472)
Accumulated other comprehensive income (loss)	29	(10)
<b>Total stockholders' equity</b>	<b>48,597</b>	<b>78,024</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 70,667</b>	<b>\$ 91,970</b>

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,		
	2015	2014	2013
<b>Revenue</b>			
Product revenue	\$ 39,029	\$ 30,328	\$ 27,204
License and other revenue	382	266	200
<b>Total revenue</b>	<u>39,411</u>	<u>30,594</u>	<u>27,404</u>
Cost of revenue	15,317	13,127	15,570
<b>Gross profit</b>	<u>24,094</u>	<u>17,467</u>	<u>11,834</u>
<b>Operating expenses</b>			
Sales and marketing	14,385	12,629	12,818
General and administrative	13,772	12,069	11,836
Research and development	37,472	31,823	22,060
<b>Total operating expenses</b>	<u>65,629</u>	<u>56,521</u>	<u>46,714</u>
<b>Loss from operations</b>	<u>(41,535)</u>	<u>(39,054)</u>	<u>(34,880)</u>
<b>Other income (expense)</b>			
Interest income	125	244	403
Interest expense	(880)	(20)	(19)
Other income (expense)	133	(6)	897
<b>Total other income (expense)</b>	<u>(622)</u>	<u>218</u>	<u>1,281</u>
<b>Loss before provision for income taxes</b>	<u>(42,157)</u>	<u>(38,836)</u>	<u>(33,599)</u>
Income tax expense (benefit)	40	(573)	44
<b>Net loss</b>	<u>\$ (42,197)</u>	<u>\$ (38,263)</u>	<u>\$ (33,643)</u>
Net loss per share, basic and diluted	<u>\$ (1.00)</u>	<u>\$ (0.93)</u>	<u>\$ (0.95)</u>
Weighted average number of shares outstanding basic and diluted	<u>42,157</u>	<u>41,346</u>	<u>35,253</u>
<b>Other comprehensive loss</b>			
Net loss	\$ (42,197)	\$ (38,263)	\$ (33,643)
Foreign currency translation adjustments	(36)	—	—
Net unrealized losses on marketable securities, net of tax	(3)	(20)	(4)
<b>Comprehensive loss</b>	<u>\$ (42,236)</u>	<u>\$ (38,283)</u>	<u>\$ (33,647)</u>

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, 2012	32,753	\$ 3	\$ 247,449	\$ (436)	\$ (190,566)	\$ 56,450
Issuance of stock in lieu of accrued bonuses	—	—	653	—	—	653
Stock-based compensation expense	—	—	3,893	—	—	3,893
Issuance of employee stock purchase plan shares	33	—	300	—	—	300
Restricted stock awards issued, net of cancellations	(122)	—	—	—	—	—
Shares issued under stock-based compensation plans	91	—	396	—	—	396
Issuance of common stock, net of offering expenses	8,765	1	80,672	—	—	80,673
Elimination of cumulative foreign currency translation adjustments upon liquidation of foreign subsidiary	—	—	—	450	—	450
Net loss	—	—	—	—	(33,643)	(33,643)
Unrealized loss on marketable securities	—	—	—	(4)	—	(4)
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 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 loss on marketable securities	—	—	—	3	—	3
Balance—December 31, 2015	42,551	\$ 4	\$ 353,233	\$ 29	\$ (304,669)	\$ 48,597

See accompanying notes to consolidated financial statements.

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

	Years ended December 31,		
	2015	2014	2013
<b>Operating activities:</b>			
Net loss	\$ (42,197)	\$ (38,263)	\$ (33,643)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,405	2,656	2,530
Amortization of premiums on investments	180	702	314
Amortization of deferred debt issuance costs	285	—	—
Stock-based compensation	9,995	5,796	3,893
Provision for bad debt	25	—	2,721
Non-cash inventory adjustments	594	450	1,779
Gain on sale of investment in preferred stock	(223)	—	(1,392)
Elimination of cumulative foreign currency translation adjustments upon liquidation of foreign subsidiary	—	—	450
Impairment of intangible asset	—	—	1,624
Other non-cash adjustments	186	185	—
Changes in operating assets and liabilities:			
Accounts receivable	(1,983)	(2,030)	(2,390)
Inventories	(1,286)	(229)	(1,313)
Prepaid expenses and other assets	(36)	(184)	(119)
Accounts payable	(757)	85	1,343
Accrued compensation	(458)	1,797	951
Other liabilities	355	(537)	(544)
<b>Net cash used in operating activities</b>	<b>(31,915)</b>	<b>(29,572)</b>	<b>(23,796)</b>
<b>Investing activities</b>			
Change in restricted cash	—	—	585
Payments for intellectual property licenses	(550)	(350)	(882)
Purchases of property and equipment	(3,756)	(5,726)	(4,270)
Purchases of marketable securities	(22,646)	(28,054)	(76,190)
Proceeds from sales of marketable securities	223	7,497	6,643
Maturities of marketable securities	46,050	56,050	1,550
<b>Net cash provided by (used in) investing activities</b>	<b>19,321</b>	<b>29,417</b>	<b>(72,564)</b>
<b>Financing activities</b>			
Proceeds from issuance of common stock	884	812	86,547
Costs incurred in conjunction with public offering	—	—	(5,510)
Principal repayment of borrowings	(22)	(56)	(766)
Costs associated with debt issuance	(718)	—	—
Proceeds from borrowings	10,000	—	166
Proceeds from stock option exercises	989	531	396
<b>Net cash provided by financing activities</b>	<b>11,133</b>	<b>1,287</b>	<b>80,833</b>
<b>Effect of exchange rate changes on cash</b>	<b>(9)</b>	<b>—</b>	<b>—</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(1,470)</b>	<b>1,132</b>	<b>(15,527)</b>
Cash and cash equivalents at beginning of year	36,855	35,723	51,250
Cash and cash equivalents at end of year	<u>\$ 35,385</u>	<u>\$ 36,855</u>	<u>\$ 35,723</u>
<b>Non-cash investing and financing activities:</b>			
Transfer of systems from property and equipment into inventory	\$ 225	\$ 256	\$ 575
Property and equipment costs incurred but not paid included in accounts payable	\$ 146	\$ 124	\$ 603
Intellectual property acquisition included in accrued expenses	\$ 800	\$ 550	\$ 450
Offering costs incurred but not paid included in other liabilities	\$ —	\$ —	\$ 65
<b>Supplemental cash flow information:</b>			
Cash paid for interest	\$ 572	\$ 20	\$ 19
Cash received for interest	\$ 305	\$ 244	\$ 403
Cash paid for income taxes, net	\$ 10	\$ 24	\$ 21

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 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.

As the reorganization was deemed to be a transaction under common control, GenMark accounted for the reorganization in a manner similar to a pooling-of-interests. Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term incentive awards and all warrants issued were exchanged for options and warrants exercisable for the common stock of the Company.

***Segment Reporting***

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

In 2015, Laboratory Corporation of America, Inc. represented 17% of the Company's total revenue. In 2014, no single customer represented more than 10% of the Company's total revenue. In 2013, Natural Molecular Testing Corporation, or NMTC, represented approximately 30% of the Company's total revenue.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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 \$304,669,000 at December 31, 2015. 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, 2015 totaled \$45,465,000. 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.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, and applicable regulations of the 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.

**Reclassifications**

The Company reclassified \$1,658,000 included in other current liabilities to accounts payable at December 31, 2014 to better align the nature of this balance. Reclassifications of prior year financial information have been made to conform to the current year presentation. None of the changes impacts the Company's previously reported consolidated net revenue, earnings from operations, net earnings or net earnings per share.

**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, 2015 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, 2015, is as follows (in thousands):

	<b>Allowance for doubtful accounts</b>	
Balance December 31, 2013	\$	2,736
Provision for doubtful accounts		—
Write-off and recoveries, net		(34)
Balance December 31, 2014	\$	2,702
Provision for doubtful accounts		25
Write-off and recoveries, net		—
Balance December 31, 2015	\$	2,727

The Company has included \$2,727,000 and \$2,702,000 in the allowance for doubtful accounts as of December 31, 2015 and 2014, respectively, for past due amounts from former customer, Natural Molecular Testing Corporation, or NMTC.

### ***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	5 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 rentals. PEPs are placed with customers for evaluation periods of up to six months. 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. Maintenance and repair costs are expensed as incurred. During the year ended December 31, 2013 the Company recorded an impairment charge included in depreciation expense of \$302,000 related to production equipment which had been built for NMTC.

### ***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. During 2013, the Company recorded an impairment charge of \$1,624,000 to general and administrative expenses related to previously capitalized payments made under a license agreement, which the Company terminated in December 2013. The Company also recorded an impairment charge of \$302,000 related to production equipment built for NMTC during 2013. The Company did not recognize any impairment charges during the years ended December 31, 2015 and 2014.

### ***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 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 generally agrees to purchase a starter kit at the time of installation and agrees to purchase a minimum volume of reagents over the life of the trial period.

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.

### ***Product Warranties***

The Company generally offers a one-year warranty for its systems 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, 2015, 2014 and 2013 is as follows (in thousands):

	2015	2014	2013
Beginning balance	\$ 195	\$ 226	\$ 217
Warranty expenses incurred	(430)	(608)	(649)
Provisions	353	577	658
Ending balance	<u>\$ 118</u>	<u>\$ 195</u>	<u>\$ 226</u>

### ***Research and Development Costs***

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

### ***Income Taxes***

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

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

### ***Stock-Based Compensation***

The Company recognizes stock-based compensation expense related to stock options, shares purchased under the Company's 2013 Employee Stock Purchase Plan, or ESPP, restricted stock 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 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 on a straight-line basis 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 include the expected term of the stock option, the expected volatility and other 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 volatility in the Company's stock price expected over the expected term of the option and is determined by review of the Company's and similar companies' historical experience.
- *Expected Dividend.* The Black-Scholes Option Pricing Model calls for 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 used in the Black-Scholes Option Pricing Model 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.

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 periods. 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, 2015 was \$36,000.

In 2010, the Company changed its functional currency from the British Pound to the U.S. Dollar. Upon the liquidation of Osmetech in the fourth quarter of 2013, \$450,000 of accumulated other comprehensive loss related to foreign currency translation was realized in other expense during 2013.

Transactions in foreign currencies were recognized using the rate of exchange prevailing at the date of the transaction. Foreign exchange gain (loss), which is included in the accompanying consolidated statements of operations, totaled \$7,000, \$19,000 and \$19,000 for the years ended December 31, 2015, 2014 and 2013, 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, 2015, 2014 and 2013 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,		
	2015	2014	2013
Options outstanding to purchase common stock	3,004	2,479	1,821
Other unvested equity awards	1,267	948	976
<b>Total</b>	<b>4,271</b>	<b>3,427</b>	<b>2,797</b>

***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,	
	2015	2014
Customer A	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 is comprised of 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 April 2015, the FASB issued Accounting Standards Update (ASU) 2015-03, Interest - Imputation of Interest. This standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability. The Company has retrospectively adopted this standard. The Company's debt issuance costs have been recognized as a direct reduction to short-term and long-term debt liability in the unaudited condensed consolidated balance sheets for all periods presented.

In August 2015, the FASB issued Accounting Standards Update (ASU) 2015-14, Revenue from Contracts with Customers deferring the previously issued ASU 2014-09. This standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for the Company beginning in the first fiscal quarter of 2018 and allows for a full retrospective or a modified retrospective adoption approach. The new standard does not have a current impact on the unaudited consolidated financial statements presented. The Company is currently evaluating the impact of ASU 2014-09 on its consolidated financial statements.

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, "Balance Sheet Classification of Deferred Taxes", an update to ASC 740, Income Taxes (“Updated”). Current U.S. GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update.

### 3. Intangible Assets, net

Intangible assets as of December 31, 2015 and 2014 consisted of the following (in thousands):

	December 31, 2015			December 31, 2014		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	\$ 3,550	\$ (1,174)	\$ 2,376	\$ 2,750	\$ (880)	\$ 1,870

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 a 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 electro-wetting technology in conjunction with the Company’s electrochemical detection. 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, the parties agreed to enter into a supply agreement relating to the manufacture and supply of certain ALL components. The agreement also provides that the Company would, upon the occurrence of certain events, 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 which the Company manufactures or are otherwise not manufactured and supplied by ALL. The Company met certain milestones in August 2013 and June 2014 resulting in payment of \$200,000 and \$350,000, respectively.

In October 2010, the Company entered into an intellectual property license agreement under which the Company previously made license fee payments totaling \$2.1 million to the licensor. The Company terminated this license agreement in December 2013 and recorded an impairment charge to general and administrative expenses for the remaining net book value of \$1.6 million at that time.

Intellectual property licenses had a weighted average remaining amortization period of 6.34 years as of December 31, 2015. Amortization expense for intangible assets amounted to \$294,000, \$227,000 and \$342,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Estimated future amortization expense for these licenses is as follows (in thousands):

<u>Years Ending December 31,</u>	<u>Future Amortization Expense</u>
2016	\$ 375
2017	375
2018	375
2019	375
2020	375
Thereafter	501
<b>Total</b>	<b>\$ 2,376</b>

### 4. Stockholders’ Equity

In August 2013, the Company completed a public follow-on stock offering of 8,765,000 shares of its common stock which generated net cash proceeds of approximately \$80,672,000.

### 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 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.

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, 2015, there were 145,297 shares available for future grant of awards under the 2010 Plan.

The following table summarizes stock option activity during the year ended December 31, 2015:

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2014	2,479,435	\$ 8.66
Granted	889,450	\$ 12.36
Exercised	(180,326)	\$ 5.46
Forfeitures	(184,548)	\$ 12.06
Outstanding at December 31, 2015	<u>3,004,011</u>	<u>\$ 9.74</u>
Vested and expected to vest at December 31, 2015	<u>2,765,180</u>	<u>\$ 9.55</u>
Exercisable at December 31, 2015	<u>1,611,828</u>	<u>\$ 7.77</u>

The weighted average fair value of options granted during the years ended December 31, 2015, 2014 and 2013 was \$6.02, \$7.45 and \$7.30 per share, respectively. Options that were exercisable as of December 31, 2015 had a remaining weighted average contractual term of 5.60 years and an aggregate intrinsic value of \$2,339,000. As of December 31, 2015, there was \$6,403,000 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average-period of 2.46 years. The intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was \$938,000, \$584,000 and \$730,000, respectively. As of December 31, 2015, there were 3,004,011 stock options outstanding, which had a remaining weighted average contractual term of 7.05 years and an aggregate intrinsic value of \$2,351,000.

#### ***Valuation of Stock-Based Awards***

The assumptions used in the valuation of stock-based awards for the years ended December 31, 2015, 2014 and 2013, are summarized in the following table:

	Years Ended December 31,		
	2015	2014	2013
Expected volatility (%)	49%	69%	74%
Expected life (years)	6.06	6.08	6.08
Risk free rate (%)	1.67%	1.82%	1.17%
Expected dividend yield (%)	—%	—%	—%

The Company is required to estimate potential forfeitures of restricted stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures is based on historical forfeiture experience and will be 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.

**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, 2015 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, 2014	173,610	\$ 4.56	741,992	\$ 11.46
Granted	—	\$ —	683,996	\$ 13.29
Vested	(133,774)	\$ 4.34	(385,503)	\$ 11.56
Forfeitures	(6,999)	\$ 4.35	(105,508)	\$ 12.98
Unvested at December 31, 2015	32,837	\$ 5.00	934,977	\$ 12.66

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, 2015, there was \$114,000 of unrecognized compensation cost related to restricted stock awards, which is expected to be recognized over a weighted average-period of 0.33 years. The total fair value of restricted stock awards that vested during the years ended December 31, 2015, 2014 and 2013 was \$580,000, \$3,466,000 and \$4,201,000, respectively.

As of December 31, 2015, there was \$7,014,000 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 2.39 years. The total fair value of restricted stock units that vested during the years ended December 31, 2015, 2014 and 2013 was \$4,457,000, \$2,121,000 and \$72,000, respectively.

The Company issued 154,929 market-based stock units with a fair value of \$18.07 per share in February 2015, which may result in the recipient receiving shares of stock equal to 200% of the target number of units. 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 reaching the market condition based on simulated future stock prices, with the following assumptions: expected volatility of 44.7% and risk free interest rate of 1.1%. The vesting and issuance of Company stock depends on the Company's stock performance as compared to the NASDAQ Composite Index. The awards vest in three equal installments on December 31, 2015, December 31, 2016 and December 31, 2017 if stock performance metrics are achieved. On December 31, 2015, an aggregate of 4,299 units were earned and vested with a total fair value of \$29,000. As of December 31, 2015, there was \$817,000 of unrecognized stock-based compensation expense related to these awards, which is expected to be recognized over a weighted average period of 2 years.

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 various 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 December 31, 2015, 10,800 units were forfeited as the related performance metrics were not achieved. As of December 31, 2015, there was \$266,000 in unrecognized stock-based compensation expense related to the remaining unvested awards.

**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,		
	2015	2014	2013
Cost of revenue	\$ 209	\$ 73	\$ 162
Sales and marketing	3,050	1,848	1,223
Research and development	2,498	1,194	613
General and administrative	4,238	2,681	1,895
Stock-based compensation expense	\$ 9,995	\$ 5,796	\$ 3,893

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, 2015, 2014 and 2013, respectively.

**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, 2015, there were 405,897 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, 2015.

A summary of ESPP activity for the year ended December 31, 2015 and 2014 is as follows (in thousands, except share, and per share data):

	Year Ended December 31,	
	2015	2014
Shares issued	122,245	88,419
Weighted average fair value of shares issued	\$ 7.22	\$ 11.20
Employee purchases	\$ 884	\$ 812

**6. Income Taxes**

The Company's income (loss) before provision (benefit) for income taxes for the years ended December 31, 2015, 2014, and 2013, respectively, was generated in the following jurisdictions (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Domestic	\$ (42,221)	\$ (37,766)	\$ (33,599)
Foreign	64	(1,070)	—
Worldwide Income (Loss)	\$ (42,157)	\$ (38,836)	\$ (33,599)

The components of income tax expense (benefit) were as follows for the years ended December 31, 2015, 2014, and 2013, respectively (in thousands):

	Years Ended December 31,		
	2015	2014	2013
<b>Current expense:</b>			
U.S. federal	\$ —	\$ —	\$ —
State	25	(573)	44
Foreign (non-U.S. entities)	20	—	—
<b>Total current expense (benefit)</b>	<b>\$ 45</b>	<b>\$ (573)</b>	<b>\$ 44</b>
<b>Deferred expense (benefit):</b>			
U.S. Federal	\$ (4)	\$ —	\$ —
State	(1)	—	—
<b>Total deferred expense (benefit)</b>	<b>\$ (5)</b>	<b>\$ —</b>	<b>\$ —</b>

The components of net deferred income taxes consisted of the following at December 31, 2015 and 2014, respectively (in thousands):

	As of December 31,	
	2015	2014
<b>Deferred income tax assets:</b>		
NOL and credit carryforwards	\$ 59,907	\$ 44,768
Compensation accruals	3,952	3,078
Accruals and reserves	2,201	2,551
State tax provision	8	8
Inventory adjustments	559	513
Intangible assets	361	355
Other	5	10
<b>Subtotal: Deferred tax assets</b>	<b>66,993</b>	<b>51,283</b>
Depreciation	(782)	(635)
Valuation allowance	(66,211)	(50,648)
<b>Net deferred income taxes</b>	<b>\$ —</b>	<b>\$ —</b>

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, "Balance Sheet Classification of Deferred Taxes", an update to ASC 740, Income Taxes ("the Update"). Current U.S. GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update.

For public business entities, the amendments in the Update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The FASB also decided to permit earlier application by all entities as of the beginning of any interim or annual reporting period. The FASB further provided that the Update may be applied to all deferred tax liabilities and assets retrospectively to all periods presented. The Company chose to adopt the Update in fiscal year ended December 31, 2015 and apply this Update on a prospective basis.

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, 2015, 2014, and 2013, respectively, as follows:

	Years Ended December 31,		
	2015	2014	2013
U.S. Federal statutory income tax rate	34.0 %	34.0 %	34.0 %
Permanent differences	(0.1)%	(0.3)%	(0.6)%
State taxes	2.4 %	2.6 %	(1.0)%
Executive compensation limitation	(0.8)%	(0.7)%	(0.4)%
Stock-based compensation	(1.4)%	(1.5)%	(0.9)%
Other	2.1 %	0.3 %	(0.9)%
Valuation allowance	(36.9)%	(32.9)%	(30.3)%
Total tax provision	<u>(0.7)%</u>	<u>1.5 %</u>	<u>(0.1)%</u>

The Company had federal net operating loss (NOL) carryforwards available of approximately \$166,400,000 as of December 31, 2015 after consideration of limitations under Section 382 of the Internal Revenue Code, or Section 382, as further described below. Additionally, the Company had state and foreign NOL carryforwards available of \$143,700,000 and \$1,100,000 as of December 31, 2015, respectively. These federal and state NOLs may be used to offset future taxable income and will begin to expire in 2025 and 2016, respectively.

Of the \$166,400,000 and \$143,700,000 of federal and state NOL carryforwards at December 31, 2015, \$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, 2015. As a result of this assessment, the Company determined that it experienced multiple ownership changes through 2015 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, 2015. 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, 2015, a valuation allowance of \$66,211,000 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, 2015, 2014 and 2013, respectively (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Beginning balance of unrecognized tax benefits	\$ —	\$ 382	\$ 382
Lapses in the statute of limitations	—	(382)	—
Ending balance of unrecognized tax benefits	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 382</u>

At December 31, 2015 and December 31, 2014, 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, 2015, 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 we have 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 \$1,233,000, \$1,147,000 and \$1,049,000 for the years ended December 31, 2015, 2014, and 2013, respectively. Pursuant to the Company's lease agreements, a portion of the monthly rental has been deferred. The balance deferred at December 31, 2015 and 2014 was \$1,445,000 and \$1,601,000, respectively.

Annual future minimum obligations for leases as of December 31, 2015 are as follows (in thousands):

<u>Years Ending December 31,</u>	<u>Amount</u>
2016	\$ 1,432
2017	1,632
2018	1,780
2019	1,907
2020	1,972
Thereafter	2,738
Total minimum lease payments	<u>\$ 11,461</u>

### *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, 2015 and 2014 was comprised of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	\$ 1,147	\$ 593
Work-in-process	693	660
Finished goods	1,214	884
	<u>\$ 3,054</u>	<u>\$ 2,137</u>

## 9. Property and Equipment, net

Property and equipment comprised of the following as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Property and equipment—at cost:		
Plant and machinery	\$ 7,728	\$ 6,737
Instruments	8,195	6,611
Office equipment	1,526	1,441
Leasehold improvements	4,311	4,050
Total property and equipment—at cost	<u>21,760</u>	<u>18,839</u>
Less accumulated depreciation	(10,364)	(7,787)
Property and equipment, net	<u>\$ 11,396</u>	<u>\$ 11,052</u>

Depreciation expense was \$3,112,000, \$2,429,000 and \$2,187,000 for the years ended December 31, 2015, 2014 and 2013, respectively. During the year ended December 31, 2015 and 2014, the Company disposed of certain assets no longer in use with a net book value of \$153,000 and \$102,000, respectively, recorded to cost of revenue, sales and marketing, research and development, and general and administrative expenses based on the assets respective use. During the year ended December 31, 2013 the Company recorded an impairment charge included in depreciation expense of \$302,000 related to production equipment which had been built for NMTC.

## 10. Loan payable

The Company had no outstanding long-term debt as of December 31, 2014. As of December 31, 2015, long-term debt consisted of the following (in thousands):

	December 31, 2015
Term Loan A	
6.9% principal	\$ 10,000
Unamortized issuance premium	(483)
Total debt, net	<u>9,517</u>
Current portion of unamortized issuance premium	373
Long-term debt	<u>\$ 9,890</u>

### Term Loans

In January 2015, the Company entered into a Loan and Security Agreement, or the LSA, with General Electric Capital Corporation, or GECC, 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. In December 2015, GECC assigned its interest in the loan to Capital One Healthcare. 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.

On March 27, 2015, the Company borrowed \$10,000,000 pursuant to Term Loan A. 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 year ended December 31, 2015 totaled \$611,000 for the stated interest and final fee accrual.

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, 2015, the Company was in compliance with all covenants under the LSA.

On September 30, 2015, the Company entered into an amendment to the LSA, pursuant to which the lenders internally reallocated certain funding commitments under the LSA between the lenders (but did not increase or reduce the aggregate amount of such commitments), and the parties adjusted certain of the Company's administrative financial reporting obligations and the dates by which certain future funding requirements must be satisfied.

### ***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, 2015, the Company had not borrowed any amounts pursuant the revolving loan facility. Interest expense recognized for the unused revolving loan facility fee for the year ended December 31, 2015 was \$34,000.

### ***Debt Issuance Costs***

As of December 31, 2015 and December 31, 2014, the Company had \$483,000 and \$90,000, 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, 2015, amortization of debt issuance costs was \$208,000, 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, 2015.

## **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, 2015 and 2014 consisted of the following (in thousands):

	December 31,	
	2015	2014
Accrued royalties	\$ 1,608	\$ 1,210
Accrued warranties	118	195
Other accrued liabilities	626	590
Total	\$ 2,352	\$ 1,995

### 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, 2015 and 2014, respectively, (in thousands):

	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

	December 31, 2014			
	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)	\$ 31,412	\$ —	\$ —	\$ 31,412
Corporate notes and bonds	—	18,387	—	18,387
U.S. government and agency securities	—	15,264	—	15,264
	\$ 31,412	\$ 33,651	\$ —	\$ 65,063

At December 31, 2015, 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, 2015 (in thousands) :

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	\$ 8,495	\$ 1	\$ (13)	\$ 8,483
U.S. government and agency securities	799	—	—	799
Commercial Paper	798	—	—	798
Total	\$ 10,092	\$ 1	\$ (13)	\$ 10,080

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

The following table summarizes the maturities of the Company's available-for-sale securities at December 31, 2015 (in thousands):

	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 10,092	\$ 10,080
Due after one year through two years	—	—
<b>Total</b>	<b>\$ 10,092</b>	<b>\$ 10,080</b>

**15. Quarterly financial data (unaudited)**

	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
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)
	Year Ended December 31, 2014 (In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Total revenue	\$ 7,913	\$ 6,555	\$ 6,300
Gross profit	\$ 4,322	\$ 3,455	\$ 3,691	\$ 5,999
Loss from operations	\$ (8,860)	\$ (11,265)	\$ (10,272)	\$ (8,657)
Net loss	\$ (8,783)	\$ (11,210)	\$ (9,658)	\$ (8,612)
Per share data:				
Net loss per common share—basic and diluted	\$ (0.22)	\$ (0.27)	\$ (0.23)	\$ (0.21)

**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 "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, 2015, 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, 2015 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, 2015 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, 2015.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2015 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, 2015, 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, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2015 consolidated financial statements of GenMark Diagnostics, Inc. and our report dated February 23, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

San Diego, California  
February 23, 2016

**Item 9B. OTHER INFORMATION**

None.

**PART III.**

**Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item is incorporated in this Annual Report by reference from the information under the captions “Board of Directors Information,” “Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” contained in the Proxy Statement to be filed in connection with our 2016 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](http://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 Ernst & Young LLP, Independent Registered Public Accounting Firm

Report of Deloitte & Touche LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2015 and 2014

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013

Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013

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.



**INDEX TO EXHIBITS**

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
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 from 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 from 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	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). †
10.10	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). †
10.11	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).†
10.12	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)*
10.13	The GenMark Diagnostics, Inc. 2014 Bonus Plan (incorporated by reference herein to our Form 8-K as filed with the SEC on March 11, 2014).*
10.14	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).*
10.15	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).*

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
10.16	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).*
10.17	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010).*
10.18	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).*
10.19	Form of Amendment of Restricted Stock, Restricted Stock Unit and/or Stock Option Agreement(s) (incorporated by reference herein to our Form 10-Q as filed with the SEC on May 6, 2014).*
10.20	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).*
10.21	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).*
10.22	Executive Employment Agreement, dated January 1, 2010, by and between Osmetech Technology Inc. and Jon Faiz Kayyem, Ph.D. (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).*
10.23	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).*
10.24	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).*
10.25	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).*
10.26	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).*
10.27	Executive Employment Agreement dated March 1, 2010, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Jeffrey Hawkins (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 13, 2011).*
10.28	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).*
10.29	Employment Offer Letter dated April 1, 2013 by and between Clinical Micro Sensors, Inc., d.b.a. GenMark Diagnostics and Ingo Chakravarty (incorporated by reference from our Form 10-Q filed on May 6, 2014).*
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 ✓

<b><u>Exhibit</u></b>	<b><u>Description</u></b>
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.