GenMark Diagnostics, Inc.
Form 10-K
March 14, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the year ended December 31, 2012

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

For the transition period from to

Commission File Number: 001-34753

GenMark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-2053069**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5964 La Place Court, Suite 100, Carlsbad, California	**92008-8829**
(Address of principal executive offices)	**(Zip code)**

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

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

As of June 29, 2012, 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 $120,171,000 based on the closing sale price for the registrant s common stock on the NASDAQ Global Market

on that date of $4.34 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 March 1, 2013 was 32,757,777. The common stock is listed on the NASDAQ Global Market (trading symbol GNMK).

DOCUMENTS INCORPORATED BY REFERENCE

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

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Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, particularly in Item 1. Business and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated herein by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act 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 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. Factors that may cause such differences include, but are not limited to, those risks described under the heading Risk Factors in Item 1A of Part I of this Annual Report.

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.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report and in the documents incorporated herein may not occur and actual results 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.

Trademarks and Trade Names

GenMark® and eSensor® 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 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.

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PART I.

Item 1. BUSINESS

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware in February 2010. GenMark 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 subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Any discussion of GenMark prior to this reorganization relates to Osmetech and its consolidated subsidiaries. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure.

References herein to we, us or our refer to GenMark Diagnostics, Inc. unless the context specifically requires otherwise.

Overview

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor® detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct biomarkers in a single sample. 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 tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within approximately 30 minutes of receipt of an extracted and amplified nucleic acid sample, our XT-8 system produces clear and accurate results. 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 target customers, which are primarily hospitals and reference laboratories. As of December 31, 2012, we had an installed base of 297 analyzers, or placements, with our customers.

We have developed eight tests for use with our XT-8 system and may expand this test menu. Four of our diagnostic tests have received FDA clearance, including our Cystic Fibrosis Genotyping Test, which detects genetic changes associated with cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual s ability to metabolize the oral anticoagulant warfarin, our Thrombophilia Risk Test, which detects an individual s increased risk of blood clots, and our Respiratory Viral Panel Test, which simultaneously detects and differentiates 14 clinically relevant viruses from patients with influenza-like illnesses. Our Respiratory Viral Panel test received 510(k) clearance from the FDA in September 2012. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to Deoxyribonucleic acid, or DNA, sequencing and other standards in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed two Hepatitis C Virus, or HCV, genotyping tests, a 3A4/3A5 genotyping test and a 2C19 genotyping test, versions of which are available for research use only (RUO).

We are also developing our next-generation instrument system, or NexGen system. We are designing the NexGen system to integrate automated nucleic acid extraction and amplification with our eSensor detection technology to enable technicians using the NexGen system to be able 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 are designing our NexGen system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

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Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the fiscal year ended December 31, 2012 and 2011 were approximately $22.1 million and $24.0 million, respectively. As of December 31, 2012, we had an accumulated deficit of $190.6 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 our NexGen system and additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Our Strategy

Our goal is to become the market leading provider of automated, multiplex molecular diagnostic testing systems. We intend to expand the use of our XT-8 system and diagnostic tests targeting especially those reference laboratories and hospitals in the United States which perform a high volume of molecular diagnostic tests. To achieve this objective, we intend to:

Grow our Installed Base of Customers. We have identified those laboratories and hospitals in the United States that we believe will be high volume customers and who will benefit from our eSensor® technology. We intend to leverage our commercial organization to drive placements of our XT-8 system. We anticipate 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 Utilization of Tests. 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.

Develop our NexGen System. We are developing our NexGen system to provide a complete sample to answer solution for our customers. The NexGen system is being designed to retain all the customer benefits of our XT-8 system, while also integrating automated nucleic acid extraction and amplification processes. These features will eliminate the need for time consuming and complex sample preparation steps and allow technicians to place a patient sample directly into our test cartridge. We have already demonstrated feasibility of direct sample to answer on a prototype NexGen system. We believe the NexGen 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 these workflow enhancements will expand our target user base from approximately 1,000 customers to approximately 5,000 or more potential customers in the United States.

Expand our Menu of Clinical Diagnostic Products. We intend to develop a broad menu of molecular diagnostic tests that we believe will satisfy important medical needs and present attractive commercial opportunities. These tests may include genotyping tests for viruses such as HCV or detection tests for panels of viruses, bacteria or fungi, such as lower respiratory tract infections.

Expand Internationally and Explore Out-Licensing Opportunities. We plan to offer our molecular diagnostic products in European and other international markets in the future. We anticipate using marketing partners and distributors as we expand internationally. We expect to supplement marketing partnerships with specialists who will train our partners sales forces and provide technical support. We also intend to explore opportunities to leverage our intellectual property position in detection technologies through licensing or the establishment of partnerships.

Revenues from external customers, net loss and total assets for the past three years are contained in our consolidated financial statements in Part II of this Annual Report.

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Our Products

Our XT-8 System

Our XT-8 system is an automated molecular diagnostic system that enables reference laboratories and hospitals to perform fast, accurate and easy-to-use molecular diagnostic tests. The XT-8 system, which employs our proprietary electrochemical detection technology, consists of a compact bench-top workstation with an integrated touch screen computer and an analyzer into which our self-contained, disposable test cartridges are inserted. Our XT-8 system is user-friendly, intuitive, requires minimal maintenance and provides laboratories with the ability to perform multiplex molecular diagnostic tests in an efficient and cost-effective manner. With a footprint of approximately 16-by-16 inches in its standard configuration, our XT-8 system takes up less bench top space than many of our competitors systems, and its standalone design allows it to be installed and used without any required laboratory modifications.

We believe that our XT-8 system and related diagnostic tests will offer reference laboratories and hospitals the following benefits:

Versatile Platform for a Broad Test Menu. Our XT-8 system has broad application across a number of areas in molecular diagnostic testing. In addition to our FDA-cleared Cystic Fibrosis Genotyping Test, Warfarin Sensitivity Test, Thrombophilia Risk Test and Respiratory Viral Panel Test, we have a pipeline of several additional products in the development or design phase in the fields of pharmacogenetics, genetic diseases, infectious diseases and cancer. We have also developed two HCV genotyping tests, a 3A4/3A5 genotyping test and a 2C19 genotyping test, each of which is available for research use only. Laboratories using our system will be able to run the additional tests we offer without any additional capital investment or operator training.

Ease of Use. Our XT-8 system eliminates the need to use complex instrumentation to generate test results. Our XT-8 system minimizes manual processing steps and streamlines data analysis, making molecular diagnostic testing available to a broad spectrum of laboratories without the need for highly skilled technicians. As a result, our XT-8 system can provide national reference laboratories with the ability to perform our menu of molecular diagnostic tests across all of their locations. We also designed our XT-8 system to require minimal maintenance.

Accuracy and Reliability. Our XT-8 system provides accurate and reliable molecular diagnostic test results. We have demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. Our XT-8 system limits technician contact with a patient sample, thereby reducing contamination risk. It also provides clear reports, minimizing the risk of human error and increasing the repeatability of test results.

Enhanced Laboratory Work Flow. Our unique platform allows for random access, or the ability to initiate any of our tests while any of our other tests are in progress, resulting in a highly convenient and flexible workflow. Our XT-8 system provides random access for up to 24 independent test cartridges. In addition, our proprietary electrochemical detection technology streamlines the sample preparation process and eliminates the need for the additional washing steps required by some other detection methods, such as optical or fluorescent detection. Laboratories using our XT-8 system can expect to obtain test results within approximately 30 minutes of receipt of the amplified DNA sample, generally resulting in a total turnaround time of under four hours.

Multiplex Capability. Our XT-8 system can detect up to 72 separate biomarkers in a single test cartridge. This allows laboratories to run multiple tests or panels on an individual patient sample in a one-step detection process. This capability reduces the time required for a laboratory to perform a diagnostic analysis that involves multiple genetic markers or infectious disease pathogens, which otherwise would require the laboratory to run multiple, separate molecular diagnostic tests.

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Prior to performing a test, a laboratory technician takes isolated DNA from the patient sample and performs an automated nucleic acid extraction and amplification step with materials supplied with our test cartridge. In some cases, the technician also performs a routine enzymatic treatment before adding our proprietary signal probes and transferring the solution into the sample compartment in our test cartridge. The technician enters sample identification and reagent information into our XT-8 system using the supplied bar code wand or on-screen keyboard and inserts the test cartridge into an open slot on the analyzer. The on-board computer automatically assimilates input information and test cartridge information from the memory chip on the test cartridge and initiates the specified test protocol. The testing process generally takes under four hours to complete, and in most cases the test results can be viewed on the built-in touch screen monitor approximately 30 minutes after the insertion of test cartridges into the instrument. Test results can also be printed out or reported through the laboratory s computer information system.

The key features of our XT-8 system include:

Key Features	Characteristics
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	Intuitive touch-screen interface and clear reports
Small Footprint	Approximately 16 inches in width and depth in its standard configuration
Random Access	Each of up to 24 test cartridge slots can be accessed independently
Minimal Maintenance	No routine maintenance or calibration required
Multiplex Capability	Detects up to 72 distinct biomarkers in a single sample

Our Test Menu

We have developed eight diagnostic tests for use with our XT-8 system, four of which have received clearance from the FDA. The majority of our revenues are derived from the sale of consumables (reagents and test cartridges) based on our proprietary eSensor® technology. For the fiscal years ended December 31, 2012, 2011 and 2010, consumables sales represented 96%, 88%, and 81% of our total revenues, respectively.

Cystic Fibrosis Genotyping Test. Our Cystic Fibrosis Genotyping Test is a multiplex genotyping test that detects a panel of mutations associated with cystic fibrosis based on guidelines published by the American College of Medical Genetics and the American College of Obstetricians and Gynecologists for screening of adult couples contemplating pregnancy. Our Cystic Fibrosis Genotyping Test demonstrated 100% accuracy in clinical studies as compared to DNA sequencing and other standards and delivers results within 30 minutes of receipt of the amplified DNA sample. Test results are summarized in an easy-to-interpret report that includes a summary carrier or non-carrier determination as well as individual carrier status for each of the 23 recommended markers. Our Cystic Fibrosis Genotyping Test received FDA clearance in July 2009.

Our Cystic Fibrosis Genotyping Test addresses a market that was estimated in 2011 at over $70 million in the United States alone. More than 10 million Americans are carriers of one mutation of the cystic fibrosis gene. The American College of Obstetricians and Gynecologists suggests that all couples who are considering having a child, or those who are expecting a child, should have genetic carrier testing for cystic fibrosis. Much of current cystic fibrosis testing is performed by national reference laboratories. With the availability of highly accurate, easy to use cystic fibrosis tests, we expect that the market will continue to decentralize through regional reference laboratories and hospitals now capable of offering this test.

Warfarin Sensitivity Test. Our Warfarin Sensitivity Test is a multiplex pharmacogenetic test for the detection of three genetic markers that are known to play a critical role in the metabolism of, and sensitivity to, warfarin. Warfarin, offered under the brand name Coumadin, is the most widely prescribed oral anticoagulant in North America and Europe and is used to prevent heart attacks, strokes and blood clots in veins, arteries and lungs. Through detection of an individual s sensitivity to warfarin, doctors are better able to accurately and

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efficiently determine the appropriate warfarin dosage level on an individual patient basis. Our Warfarin Sensitivity Test demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards and delivers results within 30 minutes of receipt of the amplified DNA sample. Our Warfarin Sensitivity Test received FDA clearance in July 2008.

Thrombophilia Risk Test. Our Thrombophilia Risk Test is a multiplex test for the detection of four common inherited genetic risk factors of thrombophilia: Factor V Leiden, Factor II prothrombin and two genetic markers in the methylenetetrahydrofolate reductase (MTHFR) gene. Thrombophilia is a condition where a person s blood clots easily or excessively placing them at risk of developing clots. Thrombophilia is a particular concern for high risk patients, including patients who are pregnant or undergoing certain surgeries. Our Thrombophilia Risk Test demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards and delivers results within 30 minutes of receipt of the amplified DNA sample. Our Thrombophilia Risk Test received FDA clearance in April 2010.

Thrombophilia is one of the most common types of blood coagulation disorders affecting 1 in 1,000 individuals. We believe the U.S. market is approximately $55 million based on statistics provided by Kalorama Information 2009, a market research firm.

Respiratory Viral Panel (RVP) Test. Our Respiratory Viral Panel Test is a multiplex test for the detection of 14 viruses, including influenza A (H1N1 and seasonal), influenza B, respiratory syncytial virus (RSV) and numerous other upper respiratory viruses. Our Respiratory Viral Panel Test received FDA clearance in September 2012.

Respiratory pathogens are a major source of illness and can lead to hospitalizations and death. According to the Centers for Disease Control, each year in the United States, on average, 5% to 20% of the population gets the flu and more than 200,000 people are hospitalized from flu-related complications. In addition, over a period of 30 years (1976-2006), estimates of flu-associated deaths in the United States ranged from a low of approximately 3,000 to a high of approximately 49,000. RSV is the most common cause of bronchitis and pneumonia in infants and young children, with up to 125,000 children hospitalized annually in the United States. One of the challenges faced by the physician assessing a patient with a respiratory illness is determining the underlying cause so that an effective treatment plan can be determined.

Hepatitis C Virus Genotyping (HCVg) Tests. Our HCV Genotyping Test and our HCVg Direct Test, each of which is currently labeled for research use only, are multiplex tests for the detection and typing/subtyping of HCV 1a, 1b, 2a/c, 2b, 3, 4, 5 and 6. According to the Centers for Disease Control, HCV infection is the most common chronic blood-borne infection in the United States with over 3.0 million people considered chronically infected. According to the World Health Organization, it is estimated that approximately 150 million people are chronically infected with HCV globally and at risk of developing liver cirrhosis and/or liver cancer, and more than 350,000 people die from HCV-related liver diseases each year. An article published in the Annals of Internal Medicine found that, in the United States, HCV is cited as the cause of death more than HIV. Based on the current treatment guidelines for HCV, a patient s genotype is a component of selecting the proper treatment strategy as well as a predictor of the likelihood of treatment success.

3A4/3A5 Genotyping Test (3A4/3A5). Our 3A4/3A5 Genotyping Test, currently labeled for research use only, is a multiplex test designed for the detection and genotyping of the *1B, *2, *3, *12, and *17 alleles of the CYP450 3A4 gene locus, and the *1D, *2, *3, *3B, *6, *7, *8, and *9 alleles of the CYP450 3A5 gene locus.

2C19 Genotyping Test (2C19). Our 2C19 Genotyping Test, currently labeled for research use only, is a multiplex test for the detection and genotyping of the *2, *3, *4, *5, *6, *7, *8, *9, *10, *13 and *17 alleles of the cytochrome P450 (CYP450) 2C19 gene locus.

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Our Tests in Development and Design

Once our NexGen system is introduced, we intend to launch two to four new tests annually. We select these tests based upon what we believe are clinically relevant targets which address unmet market needs. We are currently developing or designing the following diagnostic tests:

Infectious Disease Test Panels. We are currently designing other infectious disease test panels that would align strategically with our existing Respiratory Viral Panel Test offering by leveraging our current and future system placements in the acute care setting. The test panels we are designing fit into two categories: genotyping tests for viruses such as HCV or detection tests for panels of viruses, bacteria or fungi such as lower respiratory tract infections. Genotyping tests are run throughout the year whereas many detection tests have a seasonal component. In order to maximize the value of systems installed for infectious disease tests like our Respiratory Viral Panel Test, we may seek to develop a broad range of detection assays which have distinctly different seasonal peaks in prevalence to allow our customers to utilize our system for infectious disease testing throughout the year. Currently, several infectious disease panels and genotyping tests are in the design concept stage.

Oncology and Personalized Medicine Tests. Given the trend in oncology towards tailoring treatment to an individual s tumor type and the emerging interest in personalized medicine, we are currently researching and evaluating the development of test panels in these areas. Expanding our product offering into these two areas would align strategically with our existing products as well as development stage products by leveraging our current and future system placements in these laboratories.

Our NexGen System

We are highly focused on developing our NexGen system to provide a complete sample-to-answer solution for our customers. The NexGen system is being designed to retain all the customer benefits of our XT-8 system, while also integrating automated nucleic acid extraction and amplification processes. These features will eliminate the need for time consuming and complex sample preparation steps and allow technicians to place a patient sample directly into our test cartridge. We have already demonstrated feasibility of direct sample-to-answer on a NexGen prototype system. We believe this advancement will make our eSensor® technology attractive to the broad range of institutions that currently lack the technical or economic resources to perform molecular diagnostic testing. We believe the NexGen system will expand our target user base from approximately 1,000 to approximately 5,000 or more potential laboratories and hospitals in the United States. We believe our approach to a sample-to-answer system will achieve benefits over many other competitive multiplex systems, including an ability to perform complex multiplex tests in a high throughput, random access, efficient and cost effective manner.

Our Technology

Our eSensor® Technology

Our proprietary eSensor® technology is based on the principles of competitive 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, or biomarker, that is a focus of the 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 cartridge. We separately attach ferrocene, an electrochemically active label, to our signal probes.

Before placing the sample into our 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

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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 analyzed and interpreted by our system. Our test cartridges currently have 72 distinct electrodes, each of which can be configured to detect a different target biomarker, enabling multiplex 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 only sample preparation step required before using our XT-8 test cartridges is 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 slot in our XT-8 system. In some tests, amplified DNA is subject to an additional enzymatic treatment to produce a single-stranded-DNA.

Our XT-8 Test Cartridges. Our XT-8 test cartridges are self-contained devices specifically programmed and configured for a given diagnostic test. 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 system. The test cartridge also includes a printed circuit board chip consisting of an array of 72 gold-plated working electrodes, a silver/silver chloride reference electrode, and two gold-plated 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 component that stores information related to the cartridge such as an assay identifier, cartridge lot number and expiration date.

Our XT-8 Workstation. Our XT-8 system is a multiplex workstation that has a modular design consisting of an integrated touch screen workstation and up to three analyzers. Each analyzer contains eight modules into which individual test cartridges are placed. The test cartridge slots operate independently of each other allowing up to 24 independent test cartridges to be loaded at one time, with the remaining slots available for use at any future time while the system is running. Each slot 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 system 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 system and provides unidirectional pumping of the hybridization mixture through the cartridge during hybridization.

The touch screen workstation controls each analyzer, provides power and analyzes and stores data. Technicians can load patient identification numbers and reagent lot codes by the included bar code scanner, the touch screen or uploading a text file from a USB memory stick.

Advantages of Our eSensor® Electrochemical Signal Detection

We believe our proprietary electrochemical signal detection technology has several advantages over other signal detection platforms, including:

Robust Signal. Our capture probes are highly target specific, reducing the binding of non-target DNA and, thereby, largely eliminating interference from other components in a patient s sample, such as blood, saliva or urine. Similarly, constituents of blood that would normally interfere with fluorescence detection, such as hemoglobin or bilirubin, have no effect on the processed electronic

signals produced

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by our eSensor® technology. We believe this robust functionality will facilitate the development of integrated amplification and sample-to-answer systems for blood and other sample types.

High Sensitivity and Accuracy. Our eSensor® technology is highly sensitive in the detection of nucleic acids. Each electrode can routinely detect approximately one nanomolar of target DNA, and a sensitivity of 10 picomolar of target DNA has been achieved. Such concentrations are readily produced from patient samples using several commercially-validated amplification technologies such as PCR. Our eSensor® technology has demonstrated 100% accuracy in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test in clinical studies compared to DNA sequencing and other standards.

Streamlined Sample Preparation. Our technology directly detects the target DNA sequence with highly specific signal probes and electrode-bound capture probes. As a result, our test samples do not require many of the washing steps typically required to remove unbound target DNA and labels. We believe that our eSensor® technology can minimize sample preparation requirements. We have already demonstrated direct PCR-based genotyping from diluted whole blood without the need for DNA sample preparation or washing out of interfering substances.

Efficient Multiplexing. Each of the 72 electrodes in our test cartridge configuration acts independently of the others and produces a comprehensive and informative signal. For example, a single eSensor® electrode can measure the presence or absence of control DNA, which we use for quality control, and simultaneously indicate whether a patient sample contains zero, one or two copies of a particular sequence, corresponding to mutant, heterozygous or wild type genotypes. As a result, our eSensor® technology eliminates the need for redundancy and the averaging of multiple measurements commonly required by competing technologies.

Small Footprint with Low Maintenance. Our eSensor® technology enables users to perform hybridization and detection in a low-cost system with relatively few moving parts. In contrast, conventional microarray systems require robotic instrumentation to automate multistage fluidic handling processes. As a result, these systems are often bulky, complicated and expensive and require frequent calibration and maintenance. Our XT-8 system, for example, requires no calibration and virtually no maintenance and is self-contained in a small footprint of approximately 16-by-16 inches in its standard configuration.

Cost-Effective Development. The use of electrochemical technology allows our XT-8 system to leverage third-party advances in microelectronics such as miniaturization and manufacturing efficiencies. Many electronic components associated with our core processes are produced in large volumes at low cost and size for use in numerous fields including automotive, aerospace, information technology and medical devices. By avoiding the use of optical or fluorescent detection, we believe our eSensor® technology can be applied at low cost to numerous testing environments in addition to our current target markets, including field testing and point-of-care applications.

Straightforward Development of New Tests. Our eSensor® technology is highly flexible, and we believe the main design consideration in developing new diagnostic tests for our instrument systems is our ability to access and synthesize the appropriate capture and signal probes. Our versatile platform allows us to add new diagnostic tests to our menu or to add new content to existing diagnostic tests without modifying the system platform. This ease of assay development and our versatile platforms will allow us to focus our research and development resources on developing new commercial test products.

Functionality Outside of Molecular Diagnostics. Our eSensor® technology has broad applicability to detect a range of biomolecules. Independently, and through collaborative research with university and industry partners, we have demonstrated eSensor® detection of proteins and small molecule drugs. This versatility opens the possibility of developing mixed analyte sensors, such as tests that can detect antibodies to a certain pathogen plus the pathogen itself, or genetic variations in drug metabolism plus monitoring of the drug level itself.

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License Agreements

California Institute of Technology. We have a license from the California Institute of Technology to patents and patent applications related to nucleic acid-mediated electron transfer technology. We license certain of these patents on an exclusive basis. The license grant is worldwide, fully paid-up, and extends until the last of the underlying patents expires. The agreement is also conditioned on us paying all associated patent maintenance and prosecution fees. Either party may terminate the license agreement upon a material breach by the other party subject to a cure period. We may terminate the license agreement for any reason upon 60 days written notice.

Harvard University. We have licensed from Harvard University, or Harvard, exclusive worldwide rights to technology relating to self-assembling monolayers, or SAMs, and nucleic acid devices and methods. The license agreement provides for an upfront payment which has been paid, a maintenance/minimum annual fee which is creditable against royalties, royalties on net sales of products incorporating the underlying patents, payment of a fraction of sublicensing upfront and milestone fees and royalties and payment of all prosecution costs and maintenance fees. The license extends for the life of the underlying patents. The license agreement is terminable by Harvard upon certain events, including our insolvency or bankruptcy, our breach of the license agreement or our underreporting or underpayment of royalties, some of which are subject to a cure period. If Harvard terminates the license agreement, Harvard may, in its discretion, have a right in all sublicenses assigned for its benefit. We may terminate the license agreement for any reason upon 90 days advance written notice. Harvard retains certain rights under this license.

Marshfield Clinic. In October 2007, we exclusively licensed from Marshfield Clinic, or Marshfield, worldwide rights to a genetic marker, CYP 4F2, which has been shown to correlate with warfarin sensitivity. We paid a one-time upfront fee upon execution of the license and are required to pay quarterly net royalties, with a minimum annual royalty which began in 2009 that is subject to certain conditions. The agreement also requires sharing of sublicense royalties and a portion of any upfront fees we receive under a sublicense. The agreement extends for the life of any patent or patents issuing from the underlying patents and the pending application. The agreement automatically terminates upon our nonpayment of royalties for more than eight calendar quarters. In addition, Marshfield Clinic may terminate the agreement upon our failure to semi-annually produce and report acceptable commercial development efforts, our bankruptcy or insolvency or we otherwise breach the license agreement, subject to a cure period. We have the right to terminate the license agreement for any reason upon 90 days advance written notice. The license agreement also provides for option rights to additional markers that may be discovered by Marshfield during the term of the license agreement.

University of Washington. We have licensed, on a non-exclusive basis, from the University of Washington a biomarker relating to warfarin sensitivity that we use in our Warfarin Sensitivity Test. We paid an upfront fee upon execution of this license agreement. We are required under this license agreement to pay a quarterly royalty on net sales of products incorporating the underlying claims and to pay variable minimum royalties and a pro-rata share of ongoing patent prosecution and maintenance costs. This license extends for the life of the patent. The license agreement is terminable upon a material breach by the other party of its obligations under such license agreement, subject to a cure period, or if we become subject to receivership, winding up or bankruptcy. We may terminate the license agreement for any reason upon 60 days advance written notice to the University of Washington.

Hospital for Sick Children. In March 2006, we acquired a non-exclusive license from HSC Research and Development Limited Partnership, or HSC, to the use of various other mutations in the cystic fibrosis gene. The agreement required a one-time upfront fee, coupled with an escalating annual minimum royalty creditable against quarterly royalty payments for the life of the patent. The agreement remains in effect until the last to expire of the underlying patents. HSC may terminate the agreement for a material breach which is not cured within 60 days, and we may terminate the agreement upon 90 days written notice.

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University of Michigan. In March 2006, we acquired a non-exclusive license from the University of Michigan, or UM, and HSC to utilize the cystic fibrosis genes. We made a one-time upfront payment and are subject to escalating annual license maintenance fees against which running royalties are credited. The agreement remains in effect until the last to expire of the underlying patents. HSC/UM may terminate the agreement upon a material breach not cured within 60 days, and we may terminate the agreement upon 90 days written notice.

Roche Molecular Systems, Inc. We have a non-exclusive license from Roche Molecular Systems, Inc. to utilize a form of chemically modified thermostable DNA polymerase that is a component in some of our commercial products. We paid a one-time upfront fee for this license and are obligated to pay quarterly running royalties on net sales. The agreement remains in effect until the last to expire of the underlying patents. Either party may terminate the license agreement upon a material breach of the license agreement by the other party, subject to a cure period, or upon the filing for bankruptcy of the other party.

Siemens Healthcare Diagnostics Inc. In March 2010, we obtained a non-exclusive license from Siemens Healthcare Diagnostics, Inc., or Siemens, to certain gene alleles detected by our Thrombophilia Risk Test. Upon execution of the agreement, we paid a one-time access fee. In addition, we are obligated to pay a low single percent royalty on net sales of licensed products, which is creditable towards a designated annual minimum royalty. The agreement remains in effect until the last to expire of the licensed patents, subject to earlier termination by either party based on an uncured material breach of the other party.

Caliper Life Sciences Inc. In March 2012, we entered into a license agreement with Caliper Life Sciences Inc., or Caliper, pursuant to which we obtained a non-exclusive license under Caliper s microfluidics patent portfolio. In consideration for the license, we agreed to pay Caliper certain up-front and sales-based milestone payments, as well as a royalty on the sale of certain products. In addition, we 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.

Advanced Liquid Logic, Inc. In July 2012, we entered into a development collaboration and license agreement with Advanced Liquid Logic, Inc., or ALL. Under the terms of the agreement, we established a collaborative program with ALL to develop in-vitro diagnostic products incorporating ALL s proprietary electro-wetting technology in conjunction with our electrochemical detection. We 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 we 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 we manufacture or are otherwise not manufactured and supplied by ALL.

Market Opportunity

We believe the global market for molecular diagnostics is currently approximately $5.0 billion and will experience a growth rate of approximately 15% 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, our existing technology is suited to address a subset of this market that approximated $0.9 billion in 2012. Our XT-8 instrument and related reagents are currently only sold in the U.S. market.

We anticipate that our NexGen system currently under development would, when completed, expand the market opportunity for our technology so that we could address up to half of the total global market for molecular diagnostics. We anticipate that the market for the molecular diagnostic tests on which our NexGen system will focus to increase by more than 20% per year over the next several years. Many factors are driving growth of this market, including the expansion of genetic testing for disease predisposition, advances in

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personalized medicine, such as the tailoring of therapies to those individuals most likely to respond, and increased demand for infectious disease diagnostics panels. The markets for pharmacogenetic testing, cancer diagnostics and infectious disease diagnostic panels are anticipated to grow at approximately 30%, 17% and 14% per annum, respectively, over the next several years.

Research and Development

As of December 31, 2012, we had 47 employees focused on research and development. Our research and development expenditures were approximately $13.5 million, $8.7 million, and $6.6 million for the years ended December 31, 2012, 2011 and 2010, respectively. The increase in research and development expenses from 2011 to 2012 was primarily due to expenses incurred in connection with our NexGen system development program, and to improve our product reliability and enhance our product effectiveness in software development and product technical support.

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

Improving the Clinical and Practical Utility of our Tests. An important role of our research and development team is to help establish the clinical utility and value of our molecular diagnostic tests. We have 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.

Developing New Test Capabilities. We are developing capabilities for utilizing our eSensor® technology in protein and small molecule detection, both independently and through research collaborations. These capabilities may enhance our future menu offerings or provide us with out-licensing opportunities. We may also explore direct gene expression analysis opportunities through collaboration with oncology specialists in industry and academia. These opportunities may allow us to develop quantitative tests that are competitive with the gold standard real-time PCR tests but that are simple to perform in a multiplex manner.

Manufacturing

We manufacture our proprietary test cartridges and ancillary reagents at our headquarters 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 recently signed a lease amendment to increase our office and manufacturing facilities to approximately 53,000 square feet and believe these facilities will be adequate to meet our manufacturing needs for the foreseeable future. We outsource manufacturing of our XT-8 system to Leica Biosystems Melbourne Pty Ltd., or Leica. We also 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 carefully control the design, manufacture, testing and release of diagnostics products, as well as raw material receipt and control. In 2012, our Carlsbad, CA 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 generally ISO-certified to help assure a continual supply of high quality components.

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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 the installed base and utilization of our XT-8 system and consumables. Our products are sold in the United States through a geographically dispersed direct sales and technical specialist service organization, which is supported by a centralized team of product managers and marketing, customer support, and technical support personnel.

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

We believe the XT-8 system competes largely on the basis of improved performance and reliability, ease of use and streamlined laboratory workflow, a high value test menu with multiplexing capabilities, and a superior return on investment. These and other advantages conferred by our technology are enabling us to provide clinicians and researchers with superior molecular solutions. Our sales cycle typically includes customer evaluations and validations of our products. Upon successful validation, a customer can acquire our XT-8 system and consumables in the following ways:

Reagent Rental: The 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 is a usage fee for the equipment. Our reagent rental agreements do not typically provide for any cancellation rights by the customer.

Capital Purchase: The XT-8 system 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 commitment.

In 2013, we intend to begin implementing our initial international commercialization strategy for our NexGen system, which we expect will involve a select network of partners and distributors. We may seek to augment this effort with a team of our specialists to support our partners sales forces and provide technical support. We also intend to explore opportunities to leverage our intellectual property position in molecular diagnostics through licensing or the establishment of partnerships.

Customers

In 2012, only two customers, Natural Molecular Testing Corporation, or NMTC, and Companion Diagnostics, represented more than 10% of our total revenue. Together, these customers represented approximately 68% of our total revenues for the year ended December 31, 2012. In November 2012, we entered into a four year agreement with NMTC for the purchase of our products. In 2011, one customer, NMTC, accounted for 20% of our total revenue. In 2010, one customer, BioReference Laboratories, accounted for 12% of our total revenue.

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, 2012, we had placed 297 analyzers at 135 unique customer sites, or approximately 2.2 analyzers per customer. This compares with 167 analyzer placements at 103 unique customer sites, or approximately 1.6 analyzers per customer, as of December 31, 2011.

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The increase in analyzers placed and related revenue generated in 2012 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. We expect our clinical molecular diagnostic revenues to continue to increase in 2013.

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., Qiagen NV, Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd., 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 XT-8 system competes 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 third parties, including the California Institute of Technology and Harvard University.

We believe that our patent portfolio, including approximately 150 issued U.S. and foreign patents and numerous 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 staple 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 NexGen system. In general, patents have a term of 20 years from the application filing date or earlier claimed priority date. A majority of our issued and exclusively licensed patents will expire between 2013 and 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 2033. Our success depends to a significant degree upon our ability to police infringement, derive licensing revenues 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 trademarks registered in the U.S. include eSensor® and GenMark®.

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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 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 applicable to a device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA approval. The type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device s safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification and adherence to the FDA s current Good Manufacturing Practices, or cGMP, and Quality System Requirements, as reflected in its QSR. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or postmarket surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls and include life-sustaining, life-supporting or implantable devices, devices of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Some Class I devices that have not been so exempted and Class II devices are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require PMA approval or 510(k) de novo clearance prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process, however, the 510(k) clearance process has also become increasingly stringent and expensive. The FDA has cleared our XT-8 system with our eSensor ® Warfarin Sensitivity Test, Cystic Fibrosis Genotyping Test, Thrombophilia Risk Test and Respiratory Viral Panel Test as Class II devices via the 510(k) clearance process.

510(k) Clearance. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a device legally marketed in the United States that is not subject to PMA approval,

commonly known as the predicate device. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the

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same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended use, any change or modification that significantly affects its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, may require a new 510(k) clearance or PMA approval and payment of an FDA user fee. The determination as to whether or not a modification could significantly affect the device s safety or effectiveness is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Before we can submit a medical device for 510(k) clearance, we may have to perform a series of generally short studies over a period of months, including method comparison, reproducibility, interference and stability studies to ensure that users can perform the test successfully. Some of these studies may take place in clinical environments, but are not usually considered clinical trials. For PMA submissions, we would generally be required to conduct a longer clinical trial over a period of years that supports the clinical utility of the device and how the device will be used.

Although clinical investigations of most devices are subject to the investigational device exemption, or IDE, requirements, clinical investigations of molecular diagnostic tests, including our products and products under development, are generally exempt from the IDE requirements. Thus, clinical investigations by intended users for intended uses of our products generally do not require the FDA s prior approval, provided the clinical evaluation testing is non-invasive, does not require an invasive sampling procedure that presents a significant risk, does not intentionally introduce energy into the subject and is not used as a diagnostic procedure without confirmation by another medically established test or procedure. In addition, certain of our products must be labeled per FDA regulations for research use only-RUO or for investigational use only-IUO, and distribution controls must be established to assure that our products distributed for research, method comparisons or clinical evaluation studies are used only for those purposes.

PMA Approval. A PMA application requires the payment of significant user fees. PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA s satisfaction the safety and effectiveness of the device. A PMA application must also include, among other things, a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling.

The FDA has 45 days from its receipt of a PMA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. During this review period, the FDA may request additional information or clarification of information already provided. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

FDA review of an initial PMA application is required by statute to take between six to ten months, although the process typically takes significantly longer, and may require several years to complete. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

it is not demonstrated that there is reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested in the proposed labeling;

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the data from preclinical studies and clinical trials may be insufficient to support approval; and

the manufacturing process, methods, controls or facilities used for the manufacture, processing, packing or installation of the device do not meet applicable requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA application. If the FDA s evaluation of the PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the application or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the application approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA application. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

Approval by the FDA of new PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

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 cGMP requirements, as set forth in the QSR, which include, among other things, testing, control and documentation requirements. Non-compliance with these standards can result in, among other things, 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 approval of devices, withdrawal of marketing approvals and criminal prosecutions. We have designed and implemented our manufacturing facilities under the FDA s cGMP requirements.

Because we are a manufacturer of medical devices, we must also comply with medical device reporting requirements by reviewing and reporting to the FDA 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 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.

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 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.

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Export of Our Products. Export of products subject to the 510(k) notification requirements, but not yet cleared to market, is permitted with FDA authorization provided certain requirements are met. Unapproved products subject to the PMA approval requirements may be exported if the exporting company and the device meet certain criteria, including, among other things, that the device complies with the laws of the receiving country and the company submits a Simple Notification to the FDA when the company begins to export. If the company or device does not comply with such criteria, FDA approval must be obtained for export. To obtain FDA export approval, if required, we must meet certain requirements, which may include documentation demonstrating that the product is approved for import into the country to which it is to be exported and, in some instances, safety data to demonstrate that export of the device will not be contrary to public health or safety.

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 is intended to ensure the quality and reliability of laboratory testing in the United States. 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 selected international markets. Before doing so, we or our partners and distributors will need to receive regulatory approval. The regulatory review process for medical devices varies from country to country, and many countries also 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 a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Third-Party Payor Reimbursements

Obtaining reimbursement approval for a health care product or service from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and health economic data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payor determines that a product or service is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or comparable authorities. In addition, there is a risk that full reimbursement may not be available for high-priced products. Moreover, eligibility for coverage does not imply that any product or service will be reimbursed in all cases or at a rate that allows our customers to make a profit or cover their costs. Initial or interim reimbursements for products and services, if available, may also be insufficient to cover costs and may not be made permanent.

Successful sales of our products in the United States and other countries will likely depend on the availability of reimbursement from third-party payors such as private insurance plans, managed care organizations, and Medicare and Medicaid. Our customers have obtained reimbursement for our Cystic Fibrosis Genotyping Test, our Thrombophilia Risk Test and our Respiratory Viral Panel Test for the XT-8 system. However, Medicare and Medicaid generally do not reimburse providers who use our Warfarin Sensitivity Test. Outside of the United States, health care reimbursement systems vary from country to country, and to the extent we begin to sell our products outside the United States, we may not be able to obtain adequate reimbursement coverage, if any, for our products.

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In addition, we may develop tests in the future that do not relate to previously established current procedural terminology, or CPT, codes and we may need to obtain new CPT codes in order to obtain reimbursement. In January 2013, the Centers for Medicare & Medicaid Services, or CMS, implemented new molecular diagnostic CPT codes and retired the prior procedural codes used to bill for molecular testing. In February 2012, two major Medicare carriers issued new molecular pathology pricing codes. Certain tests to identify specific genes or analytes which have been regularly used by the medical community for a number of years and, in certain cases, established as a standard of care in making therapy decisions, including certain of the products we currently sell, were previously available for reimbursement under the prior coding system. However, under the new coding system, some of these tests may now be denied reimbursement as investigational or experimental, or may be subject to significantly reduced reimbursement rates.

Reimbursement by a third-party payor depends on a number of factors, including applicable coverage policies and limitations, the level of demand by health care providers and the payor s determination that the use of a new product is medically necessary and represents a clinical advance. In addition, both government and non-government third-party payors routinely limit reimbursement coverage and reimbursement amounts for diagnostic tests. If our customers cannot receive sufficient levels of reimbursement when using our products, our ability to sell them could be significantly constrained.

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. 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. 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 subjects the manufacturer to significant civil monetary penalties.

Employees

As of December 31, 2012, we had 130 employees. Approximately 47 are involved in research and development, 37 in operations, manufacturing and quality assurance, 28 in sales and marketing, and 18 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.

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Corporate and Available Information

Our principal corporate offices are located at 5964 La Place Court, Carlsbad, California.

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

The public may read and copy any materials that we file with the SEC at the SEC s Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at (202) 551-8090. The SEC also maintains electronic versions of our reports on its website at www.sec.gov.

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 be successful in developing our NexGen system and its related test menu.

Achieving profitability and our medium to long-term growth projections will require the successful development and commercialization of our NexGen system and its related test menu. We are designing this system to integrate automated nucleic acid extraction and amplification with our eSensor® technology to allow technicians to be able to place patient samples directly into our test cartridges and obtain results with significantly reduced or no technician hands-on processing time. The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, the development of the NexGen system involves multiple technologies and third party collaboration partners, and we may not be successful in completing the development of all the currently intended features and benefits of the system or effectively managing the complexities of the development program.

Although we have significant experience with our proprietary eSensor® electrochemical detection technology, we have not thus far developed a complete sample-to-answer diagnostic instrument system. Doing so will require the successful convergence of our eSensor® technology with a number of additional technologies with which we have limited knowledge and experience and for which we must rely on a number of collaboration partners. For example, in July 2012, we entered into a Development Collaboration and License Agreement with Advanced Liquid Logic, Inc., or ALL, which established a collaborative program to develop in-vitro diagnostic products incorporating ALL s proprietary electro-wetting technology in conjunction with electrochemical detection. We also rely upon our collaboration partners to assist us with other technical aspects of our NexGen development program. While we have signed agreements with each of our collaboration partners, we cannot completely control the resources our collaboration partners dedicate to our NexGen development program. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully, in a timely manner or on

budget, or if we are otherwise unsuccessful in effectively managing the complexities of our NexGen development program, the development or commercialization of our NexGen system could be delayed or terminated, or could cost significantly more than our current estimates.

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Our financial results will depend on the acceptance and increased demand among reference laboratories, hospitals and the medical community of our molecular diagnostic technology and products.

Our future success depends on the acceptance 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 molecular diagnostic testing methods.

Medical offices and many hospitals outsource their molecular diagnostic testing needs to national or regional reference laboratories. Our business success depends on our ability to convince these target laboratories and hospitals to perform these tests internally with our products if they have historically outsourced their testing needs, or to replace their current 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 and ease of use of our diagnostic systems 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 of our menu of available diagnostic tests relative to our competitors;
- our success in training reference and hospital-based laboratories 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 to the healthcare and patient communities. Recommendations of government agencies or these other organizations may relate to such matters as usage, 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.

If third-party payors do not reimburse our customers for the use of our products or if reimbursement levels are set too low for us to sell our products at a profit, our ability to sell our products and our results of operations will be harmed.

We sell our products to hospital-based and reference laboratories, substantially all of which receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid, other domestic and foreign government programs, private insurance plans and managed care programs. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor s determination that use of a product is:

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

cost effective; and

neither experimental nor investigational.

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Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental or investigational.

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. For example, Medicare and Medicaid generally do not reimburse providers who use our Warfarin Sensitivity Test. 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 reference laboratories, public health institutions and hospitals electing to use separate tests to screen for each disease 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 multiple test results.

In the United States, the American Medical Association, or AMA, generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, codes, which are necessary for our customers to bill and receive reimbursement for our diagnostic tests. Once the CPT code is established, CMS, which is responsible for implementing the Medicare program, establishes payment levels and coverage rules under Medicare. Private payors establish rates and coverage rules independently. We cannot guarantee that any of our tests are or will be covered by the CPT codes that we believe may be applied to them or that any of our tests or other products will be approved for coverage or reimbursement by Medicare, Medicaid or any third-party payor.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Increasingly, Medicare, Medicaid and other third-party payors are challenging the prices charged for medical services, including clinical diagnostic tests. In addition, payment methodologies may be subject to changes in healthcare legislation. In February 2012, President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation requires CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. Levels of reimbursement may continue to decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may harm the demand and reimbursement available for our products, which in turn, could harm our pricing and sales. If our customers are not adequately reimbursed for our products, they may reduce or discontinue purchases of our products, which would cause our revenues to decline.

In January 2013, CMS implemented new molecular diagnostic CPT codes and retired the prior procedural codes used to bill for molecular testing. In February 2012, two major Medicare carriers issued new molecular pathology pricing codes. Certain tests to identify specific genes or analytes which have been regularly used by the medical community for a number of years and, in certain cases, established as a standard of care in making therapy decisions, including certain of the products we currently sell, were previously available for reimbursement under the prior coding system. However, under the new coding system, some of these tests may now be denied reimbursement as investigational or experimental, or may be subject to significantly reduced reimbursement rates. If the clinical validity and utility of these tests cannot be established to the satisfaction of insurance carriers and third party payors, or the level of reimbursement for these tests is significantly reduced, some of our customers would be negatively affected, which, in turn, would adversely affect our revenues.

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

We have a few large customers that generate a significant amount of our revenue. Our two largest customers, NMTC and Companion Diagnostics, accounted for approximately 68% of our total revenue for the fiscal year ended December 31, 2012. While we have signed contracts with our significant customers, we may lose a significant customer if any existing contract with such customer expires without being extended, renewed, renegotiated or replaced or is terminated by the customer prior to expiration, to the extent such early termination is permitted by the applicable contract, or if the customer is unable to perform its obligations due to bankruptcy or other financial distress. The loss of any significant customer or a significant reduction in the amount of product ordered by any of our significant customers would adversely affect our revenue, results of operations and cash flows.

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. We obtained FDA clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We initially offered our XT-8 system and our Warfarin Sensitivity Test in July 2008, our Cystic Fibrosis Genotyping Test in July 2009, our Thrombophilia Risk Test in April 2010, and our Respiratory Viral Panel Test in September 2012. Our net losses were approximately $22.1 million and $24.0 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had an accumulated deficit of $190.6 million. We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing operations, primarily related to our commercial organization (sales and marketing), research and development and regulatory activities, maintaining our existing intellectual property portfolio, obtaining additional intellectual property rights and investing in corporate infrastructure. Although we believe that we will become cash flow positive over the next few years, 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.

Although we have recently remediated a material weakness in our internal control over financial reporting, if we are unable to maintain the effectiveness of our internal controls, our financial results may not be accurately reported.

Management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2011 reported a material weakness in our internal control over financial reporting related to the supervision and review of our financial closing and reporting process, as described in our Annual Report on Form 10-K for the year ended December 31, 2011. During 2012, we devoted significant time and resources to the remediation of the material weakness that included, but was not limited to:

- evaluating our Finance Department s management and staff qualifications, which resulted in us making certain personnel changes, including the replacement of our Chief Financial Officer, Controller and certain accounting staff;
- redesigning and implementing structured and formalized internal control procedures;
- implementing new control procedures over the utilization of external resources; and

developing and initiating a plan for the deployment of additional software systems to assist in automating and controlling certain financial processes.

Although further and ongoing efforts will continue in 2013 and beyond to enhance our internal control over financial reporting, we believe that our remediation efforts now provide the foundation for compliance with the Committee of Sponsoring Organizations of the Treadway Commission (COSO) framework. As a result, our

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assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012 no longer reports this material weakness or any other material weakness over financial reporting, and the audit report of our independent registered public accounting firm no longer expresses an adverse opinion on the effectiveness of our internal control over financial reporting as of December 31, 2012.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting in accordance with accounting principles generally accepted in the United States. Because the inherent limitations of internal control over financial reporting cannot guarantee the prevention or detection of a material weakness, we can never guarantee a material weakness over financial reporting will not occur, including with respect to any previously reported material weaknesses. Any future material weakness could result in material misstatements in our financial statements or cause us to fail to meet our reporting obligations. In addition, if we or our auditors are unable to certify that our internal control over financial reporting is effective, we may be subject to sanctions or investigations by regulatory authorities such as the SEC or The NASDAQ Global Market, and we could lose investor confidence in the accuracy and completeness of our financial reports, which would materially harm our business, the price of our common stock and our ability to access the capital markets.

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 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 components are custom-made by only a few outside suppliers. In certain instances, we have a sole source supply for certain key product components. If we are unable to satisfy our forecasted demand from existing suppliers for our kits and are unable to find alternative suppliers at reasonably comparable prices, it could have a material adverse effect on our business, financial condition and results of operations. Additionally, 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 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;

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- 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; 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 to repair or replace and could require substantial lead time 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 the XT-8 system and tests and would have a material adverse effect on our business, financial condition and results of operations. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We have limited sales and marketing experience and are currently reliant on the commercial success of our XT-8 system and its related test menu to fund our current operations and development programs.

We currently market our XT-8 instrument system and four FDA-cleared diagnostic tests. In addition, we have several diagnostic tests in the research, development or design stage. We have primarily placed our XT-8 systems with customers at no initial charge through reagent rental agreements, under which customers commit to purchase minimum quantities of test cartridges and reagents (consumables) over a period of generally 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 expect sales of consumables associated with our XT-8 system will account for the vast majority of our revenues for at least the next several years. 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 development of our NexGen system and its related test menu. As a result, to the extent that our XT-8 system and our existing and future diagnostic and research products are not commercially successful or are withdrawn from the market for any reason, our operating results, financial condition and critical 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 the XT-8 system and its related test menu 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 NexGen 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

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compete with our XT-8 system and its related test menu, our revenues and our ability to achieve profitability will be significantly impaired.

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 many companies in the United States 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 Corporation; Nanosphere, Inc.; BioFire Diagnostics; Qiagen NV; Abbott Molecular Diagnostics, a division of Abbott Laboratories; and Hologic, Inc.;

- 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; BioFire Diagnostics; Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd.; and Abbott Molecular Diagnostics.

Our diagnostic tests also face competition from LDTs developed by national and regional reference laboratories and hospitals. Such LDTs may not 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 and our competitors improve their current products and expand their menu of diagnostic tests. Many of our current competitors, as well as many of our 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. If we fail to effectively compete and keep pace with emerging technologies, our systems and related tests will become uncompetitive and our market share will decline, which would 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 in the research and development of our NexGen instrument and related diagnostic tests to expand our future product offerings. Our diagnostic products are subject to 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental regulations, directives and/or entities prior to their marketing outside the United States. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510(k) clearance, pre-market approval or foreign regulatory approvals.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals and to affix the CE mark

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to market a medical device can be costly and time consuming. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510(k) of the FDCA, or is the subject of an approved PMA, unless the device is specifically exempt from those requirements. It generally takes from four to twelve months from submission to obtain 510(k) clearance, and from one to three years from submission to obtain premarket approval; however, it may take longer, and 510(k) clearance or premarket approval may never be obtained. Similarly, we may not be able to obtain CE Certificates of Conformity necessary to affix the CE mark on our medical devices on a timely basis, if at all. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process.

A PMA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device for its intended use. The FDA also recently initiated a review of the pre-market clearance process in response to internal and external concerns regarding the 510(k) program. In January 2011, the FDA announced 25 action items designed to make the process more rigorous and transparent. Some of these proposals, if enacted, could impose additional regulatory requirements upon us 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. In addition, an important part of the European Union, or EU, conformity assessment process prior to CE marking of medical devices is a review of related clinical data. While a prospective clinical study may not be required in the EU, all medical devices must have accompanying clinical data. The extent of this data is dictated by the classification of the device. Implantable devices and certain devices classified as Class III devices require clinical investigations to be performed unless it is duly justified to rely on existing clinical data.

Delays in receipt of, or failure to obtain, clearances or approvals for future products, including our NexGen system 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 have limited experience in filing FDA applications for 510(k) clearance and pre-market approval and in securing foreign governmental authorizations. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. There can be no assurance that we will obtain or maintain any required clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining clearance or approval of our products by the FDA or relevant foreign regulatory bodies, or any failure to maintain compliance with FDA or foreign regulatory requirements, could harm our business, financial condition and results of operations.

We derive a significant portion of our revenues from the sale of RUO tests. Under the terms of recent FDA guidance, the marketing of our RUO tests to certain clinical laboratory customers for use as LDTs may be limited if the FDA were to change its existing policy of exercising enforcement discretion with respect to LDTs. Accordingly, if the FDA imposes significant changes to the regulation or enforcement of LDTs, including our RUO tests that are used as LDTs, it may be more challenging for us to market some of our RUO products and we may be required to terminate those RUO product sales, conduct clinical studies and make submissions of our RUO products to the FDA for clearance or approval, which could reduce our revenues or increase our costs and adversely affect our operations or financial condition.

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 also undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the

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Health Care and Education Reconciliation Act, or the PPACA. While the PPACA involves expanding coverage to more individuals, it includes new regulatory mandates and other measures designed to constrain medical costs. Among other requirements, the PPACA also imposes a 2.3% excise tax on sales of medical devices by manufacturers that is expected to cost the medical device industry up to $20 billion over the next decade. 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. Complying with PPACA could significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

In August 2011, the President signed into law the Budget Control Act of 2011, which may result in such changes as aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. The full impact on our business of the PPACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the medical device industry generally.

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 diagnostic 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.

In addition, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing. For this reason, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed or may in the future file patent applications covering our products or technology similar to ours. Under the first to invent rules applicable to patents filed before March 2013, any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office, or PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

There is a substantial amount of litigation involving patent and other intellectual property rights in the medical device, biotechnology and pharmaceutical industries generally. From time to time we may become engaged in litigation with third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. If a third party claims that we or any collaborator infringes its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent

owner s attorneys fees;

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a court prohibiting us from selling or licensing our product unless the third party licenses its product rights to us, which it is not required to do;

if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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 patents. 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 over 150 issued U.S. and foreign patents and numerous pending applications. In general, patents have a term of 20 years from the application filing date or earlier claimed priority date. A majority of our issued and exclusively licensed patents will expire between 2013 and 2021, with approximately one half of the patents expiring by 2018. Several of our pending applications have the potential to mature into patents that might expire between 2028 and 2033. However, patents may not be issued based on any pending or future patent applications owned by or licensed to us and, moreover, issued patents owned 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 have also licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we fail to comply with our material obligations under any of our patent license agreements, the licenses may be terminated and we could lose license rights that are important to our business. Furthermore, additional licenses we may need may not be available to us on commercially reasonable terms, or at all, which could adversely affect our results of operations and growth prospects.

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

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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 U.S. are interpreted. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the PTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011 the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the United States from a first-to-invent system to a first to file system and alter the processes for challenging issued patents. These changes may materially affect the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and patents of our collaborators and licensors. The patent situation in the medical device and diagnostic fields outside the United States is even more uncertain.

We have a number of foreign patents and applications. However, the laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in obtaining, protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

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 expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. 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 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. 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 obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations and place encumbrances on our assets. 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.

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If we are unable to retain key members of our senior management and scientists 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 sales 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.

We may not be able to manage our anticipated growth, and we may experience constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand.

Demand for our Respiratory Viral Panel Test can be seasonal based upon influenza outbreaks. Also, unanticipated changes in customer demand for our products may result in constraints or inefficiencies related to our manufacturing, sales force, implementation resources 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. Similarly, over-expansion or investments in anticipation of growth that does not materialize, or develops more slowly than we expect, could harm our financial results and result in overcapacity.

To manage our anticipated future growth effectively, we must enhance our manufacturing 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. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of new products or enhancements of existing products. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our revenue could grow more slowly than expected and we may not be able to achieve our research and development and commercialization goals. Our failure to manage our anticipated growth effectively could have a material adverse effect on our business, operating results or financial condition.

We may have difficulties scaling our manufacturing operations and may experience manufacturing delays or component shortages that could limit the growth of our revenue.

To date, we have produced our products in limited quantities relative to the quantities necessary to achieve our desired revenue growth. We recently completed a facility expansion project designed to increase our future manufacturing capabilities. Nevertheless, we may not be able to produce sufficient quantities of our products or maintain consistency between differing lots of consumables. If we encounter difficulties in scaling our manufacturing operations as a result of, among other things, quality control and quality assurance issues and availability of components and raw material supplies, we will likely experience reduced sales of our products, increased repair or re-engineering costs due to product returns, and defects and increased expenses due to switching to alternate suppliers, any of which would reduce our revenues and gross

margins.

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Although we attempt to match our parts inventory and production capabilities to estimates of marketplace demand, to the extent system orders materially vary from our estimates, we may experience continued constraints in our systems production and delivery capacity, which could adversely impact revenue in a given fiscal period. Should our need for raw materials and components used in production continue to fluctuate, we could incur additional costs associated with either expediting or postponing delivery of those materials.

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 shares of 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.

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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 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 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 or 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 the third quarter of 2012, we formalized our relationship with Leica, the contract manufacturer of our XT-8 instrument system. 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.

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

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

We may 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 are outside of our control. These factors include:

- the time and resources required to develop, and conduct clinical studies and obtain regulatory clearances for, additional diagnostic tests;

the expenses we incur for research and development required to maintain and improve our technology, including developing our NexGen 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;

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- the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution expenses;
- the expenses we incur in licensing biomarkers 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 XT-8 system 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. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a shortfall in demand for our products could have an immediate and material impact on our business and financial condition.

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

As a public company listed in the United States, we incur significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC 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.

Current economic conditions and the 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 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 and such losses have historically been within our expectations and the provisions established, we may not continue to experience the same loss rates that we have in the past, especially given the current turmoil of the worldwide economy. Additionally, these economic conditions and market turbulence may also impact our suppliers causing them to be unable to supply in a timely manner sufficient quantities of customized components, thereby impairing our ability

to manufacture on schedule and at commercially reasonable costs.

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Providing XT-8 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 these 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 continue not to 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.

Our corporate structure may create tax inefficiencies.

As a result of our reorganization in 2010 and prior to the reorganization steps that took place in June 2011 (as described below), Osmetech was a wholly-owned subsidiary of GenMark and a controlled foreign corporation for U.S. federal investments of Osmetech that otherwise would not be currently taxable under general tax rules may have become taxable. In addition, conveyance of intellectual property rights from one subsidiary to another could create taxable income. Distributions from GenMark to its operating subsidiaries or amongst the U.S. operating subsidiaries of GenMark could have been subject to additional U.S. and foreign income tax withholding and result in lower profits. During the quarter ended June 30, 2011, the Company underwent a corporate reorganization intended to simplify its U.S. entity structure. As part of the reorganization, Osmetech Technologies, Inc. merged into Clinical Micro Sensors, Inc., with Clinical Micro Systems, Inc. surviving. Additionally, Osmetech plc converted to a U.K. limited company for U.K. legal and tax purposes and made an entity classification election to be treated as an entity disregarded from GenMark Diagnostics, Inc. for U.S. federal income tax purposes. The reorganization did not trigger any material U.S. federal or U.K. income tax expense. In September 2012, as one of the final steps in the reorganization, we filed to liquidate Osmetech plc. It is anticipated that the post-reorganization structure will allow GenMark Diagnostics, Inc. to elect to file a consolidated U.S. federal income tax return with its remaining U.S. subsidiaries, Clinical Micro Systems, Inc. and Osmetech, Inc. As a result of these steps, all operations will be included in a U.S. federal consolidated tax return and many of the inefficiencies described above will be eliminated on a going-forward basis, however, the reorganization may result in additional tax liabilities to us.

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

As of December 31, 2012, we had net operating loss (NOL) carryforwards of approximately $121.2 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2032. Section 382 of the U.S. Internal Revenue Code, as amended, or the Code, generally imposes an annual limitation on the amount of NOL carryforwards that might 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. As of December 31, 2012, we estimated that approximately $63.7 million of U.S. federal net operating losses may be utilized in the future based on limitations that we have calculated 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 deferred net assets.

We also had non-U.S. NOL carryforwards of approximately $30.4 million as of December 31, 2012. As a result of Osmetech plc entering into liquidation, our expectation is that the $30.4 million of non-U.S. NOL carryforwards will not be utilized and, therefore, we have not accounted for them as a deferred tax asset.

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 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 meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Information technology systems implementation issues or security threats 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 or any unauthorized access to our information 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.

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-

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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. 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 could likely harm on our business, financial condition and results of operations.

Beginning in 2013, the PPACA also imposes new reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. Failure to submit required information may result in significant civil monetary penalties. We expect compliance with the PPACA 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.

State and federal authorities have aggressively targeted medical device companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions which would materially harm our business.

To the extent we commence commercial operations overseas, 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.

We may be unsuccessful in our long-term goal of expanding sales of our product offerings outside the United States.

Assuming we receive the applicable regulatory approvals, we intend to market our diagnostic products outside the United States through third-party distributors. These distributors 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

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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, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical studies and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. The regulatory approval process outside the United States may include all of the risks associated with obtaining FDA approval, as well as additional risks. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals 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.

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.

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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, and the project totals approximately 160,000 rentable square feet. 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. We believe that our current and future 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.

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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 periods indicated, the quarterly high and low sales prices per share of our common stock as reported on The NASDAQ Global Market.

	High	Low
Year Ended December 31, 2012		
First Quarter	$ 4.73	$ 3.63
Second Quarter	$ 5.10	$ 3.75
Third Quarter	$ 9.50	$ 4.42
Fourth Quarter	$ 10.24	$ 7.55
Year Ended December 31, 2011		
First Quarter	$ 5.34	$ 3.62
Second Quarter	$ 6.95	$ 3.83
Third Quarter	$ 6.50	$ 4.27
Fourth Quarter	$ 5.90	$ 4.00

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 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.

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Issuer s Purchases of Equity Securities

In connection with our grant of restricted stock awards to employees, at the election of the recipient, the number of shares issued on the date that the restricted stock vests is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. The following table sets forth information about repurchases of our common stock to cover employee income tax withholding obligations in connection with the vesting of restricted stock awards under our 2010 Equity Incentive Plan, or the 2010 Plan, for the three months ended December 31, 2012 (shares in thousands):

Period of Repurchase	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicity Announced Plan or Program
October 1, 2012 October 31, 2012	403	$ 8.71	
November 1, 2012 November 30, 2012	306	9.07	
December 1, 2012 December 31, 2012	738	9.91	
Total	1,447	$ 9.40	

Stockholders

The last reported sale price of common stock on March 1, 2013 as reported on the NASDAQ Global Market was $10.31. As of March 1, 2013, there were 9,066 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. 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 operations data presented below of GenMark Diagnostics, Inc. for the years ended December 31, 2012, 2011 and 2010 and the selected consolidated balance sheet data of GenMark Diagnostics, Inc. as of December 31, 2012, 2011 and 2010 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 financial statements of operations data of Osmetech plc presented below for the years ended December 31, 2009 and 2008 and the selected consolidated balance sheet data of Osmetech plc as of December 31, 2009 and 2008 have been derived from audited consolidated financial statements of Osmetech plc, not included in this Annual Report, which have been prepared in accordance with U.S. GAAP.

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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.

	Year ended December 31,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Product revenue	$ 20,211	$ 4,700	$ 2,341	$ 911	$ 560
License and other revenue	258	309	223	88	87
Total revenue	20,469	5,009	2,564	999	647
Cost of sales	11,640	6,206	3,979	4,332	3,238
Gross profit (loss)	8,829	(1,197)	(1,415)	(3,333)	(2,591)
Operating expenses:					
Sales and marketing	6,378	4,969	4,555	3,182	3,394
General and administrative	10,806	8,960	7,415	8,289	9,633
Research and development	13,536	8,737	6,646	5,634	13,423
Total operating expenses	30,720	22,666	18,616	17,105	26,450
Loss from operations	(21,891)	(23,863)	(20,031)	(20,438)	(29,041)
Other income (expense):					
Foreign exchange gain (loss)	6	6	(1)	304	505
Interest income (expense), net	(49)	(74)		33	420
Therapeutic discovery credit			1,644		
Other income (expenses), net	(21)	13			
Total other income (expense)	(64)	(55)	1,643	337	925
Loss before income taxes	(21,955)	(23,918)	(18,388)	(20,101)	(28,116)
Provision for income taxes	(148)	(52)	(15)	138	(247)
Net loss from continuing operations	$ (22,103)	$ (23,970)	$ (18,403)	$ (19,963)	$ (28,363)
Net loss per share (basic and diluted)	(0.84)	(1.45)	(1.88)	(4.41)	(28.13)
Weighted average number of shares outstanding	26,215	16,572	9,797	4,527	1,008

	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash and cash equivalents and short-term investments (1)(2)(3)	51,250	30,320	18,329	16,483	8,822
Total assets	68,016	38,186	26,314	19,333	15,175
Long-term liabilities	2,392	1,171	1,307	795	769
Total liabilities	11,566	7,552	5,247	4,009	5,238
Accumulated deficit	(190,566)	(168,463)	(144,493)	(126,090)	(106,127)
Total stockholders equity (1)(2)(3)	56,450	30,634	21,067	15,325	9,937

(1)

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.

(2) 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.

(3) In June 2010, we closed our initial public offering, in which we sold approximately 4.6 million shares of common stock at a price to the public of $6.00 per share. We raised approximately $22.6 million in net proceeds.

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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 Diagnostics, Inc., or GenMark, plc, was formed by Osmetech plc or Osmetech as a Delaware corporation in February 2010. GenMark 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 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.

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor® detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 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 tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within approximately 30 minutes of receipt of an extracted and amplified nucleic acid sample, our XT-8 system produces clear and accurate results. 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 target customers, which are hospitals and reference laboratories. As of December 31, 2012, we had an installed base of 297 analyzers, or placements, with our customers.

Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the years ended December 31, 2012, 2011 and 2010 were approximately $22.1 million, $24.0 million and $18.4 million, respectively. As of December 31, 2012, we had an accumulated deficit of $190.6 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 our NexGen system and additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Our Products and Technology

We have developed eight tests for use with our XT-8 system and may expand this test menu. Four of our diagnostic tests have received FDA clearance, including our Cystic Fibrosis Genotyping Test, which detects genetic changes associated with cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual s

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ability to metabolize the oral anticoagulant warfarin, our Thrombophilia Risk Test, which detects an individual s increased risk of blood clots, and our Respiratory Viral Panel Test, which simultaneously detects and differentiate 14 clinically relevant viruses from patients with influenza-like illnesses. Our Respiratory Viral Panel test received 510(k) clearance from the FDA in September 2012. Our eSensor® technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We also have developed two HCV genotyping tests, a 3A4/3A5 genotyping test and a 2C19 genotyping test, versions of which are available for research use only (RUO).

We are also developing our NexGen system. We are designing the NexGen system to integrate automated nucleic acid extraction and amplification with our eSensor® detection technology to enable technicians using the NexGen system to be able 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 are designing our NexGen system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

Revenue

Revenue from continuing operations includes product sales, principally of our diagnostic tests for use with our XT-8 system. We primarily place our XT-8 system with customers through a reagent rental agreement, under which 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 system for sale.

Revenue also includes licensing revenue from the out-licensing of our electrochemical detection technology. In addition, revenue generated from service agreements recognized using the proportional performance method of accounting is included in this category. 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.

Our growth plans focus primarily on reagent rental agreements with some sales of our current XT-8 system and eventual sales of our NexGen system that is currently under development. We do not anticipate any sales of our NexGen system in 2013. We plan to expand our base of customers and systems as well as add more tests for use with our existing and placed systems. We believe these developments will drive accelerated use of our test cartridges, which we expect to be our primary source of revenue.

Cost of Sales

Cost of sales includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable test kits for our XT-8 system, including royalties on product sales. Cost of sales also includes depreciation on revenue generating systems that have been placed with our customers under a reagent rental agreement, 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 sales relative to revenue, if manufacturing volumes are not able to fully absorb operating costs. Our XT-8 systems are procured from a contract manufacturer and generally capitalized as fixed assets and depreciated on a straight line basis over their useful life as a charge to cost of sales. We expect our cost of sales to increase as we place additional XT-8 systems and manufacture and sell an increasing menu of accompanying diagnostic tests; however, we expect our gross margins to increase as manufacturing efficiencies, improved procurement practices, instrument reliability increases and other improvements decrease costs as a percentage of sales.

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Sales and Marketing Expenses

Sales and marketing expenses include those costs associated with our direct sales force, sales management, marketing, technical support and business development activities. These expenses primarily consist of salaries, commissions, benefits, share-based compensation, travel, advertising, promotions, samples and trade shows. We expect sales and marketing costs to increase as we scale-up our commercial efforts to drive an increased customer base.

Research and Development Expenses

Research and development expenses primarily include expenses related to the development of our NexGen system, including expanding the menu of our instrument test cartridges. These expenses also include certain clinical study expenses incurred in the process of preparing for FDA clearance for these products, intellectual property costs and quality assurance expenses. The expenses primarily consisted of salaries, benefits, share-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. We expect research and development costs to increase as we develop our NexGen system and increase the development of new tests for our instrument systems.

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, share-based compensation costs, independent auditor costs, legal fees, consultants, travel, insurance, and public company expenses, such as stock transfer agent fees and listing fees for NASDAQ.

Foreign Exchange Gains and Losses

Transactions in currencies other than the functional currency are translated at the prevailing rates on the dates of the 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. Since the initial public offering, foreign exchange gains and losses are primarily related to amounts due under a single license agreement, which are denominated in Euros.

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 account for income taxes in accordance with ASC (Accounting Standards Codification) Topic 740, Income Taxes. Under ASC Topic 740, deferred taxes are provided on an asset and liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and the tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

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Critical Accounting Policies and Significant Judgments and Estimates

Revenue

We recognize revenue from product sales and contract 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 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, revenue is generally recognized upon shipment of the unit consistent with contract terms. When a system is placed free of charge under a reagent rental agreement, we retain title to the equipment and the system remains capitalized on the balance sheet under property and equipment. Under our reagent rental agreements, our customers pay a system usage fee, which is included in each test cartridge purchased. Our reagents and diagnostic test cartridges are priced to include the system usage and maintenance of the system and are included in product revenue in our consolidated financial statements.

We sell our durable systems and disposable test cartridges primarily through a direct sales force in the United States. The system price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on system 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. Revenue from service agreements is recognized using the proportional performance method of accounting.

In those cases where we bill shipping and handling costs to customers, the amounts billed are classified as other revenue.

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 systems, 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 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.

Long-Term Investment

In July 2012, we purchased $1,000,000 in preferred stock of a collaborative development and licensing partner and reported the amount in the accompanying consolidated balance sheets as an other long-term asset.

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Impairment of Long-Lived Assets

We assess the recoverability of long-lived assets, including intangible assets and systems 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. In the years ended December 31, 2012 and 2011, no impairment charges were recorded.

Share-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 Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option s expected term and the price volatility of the underlying stock. These assumptions include:

Expected Term. Our expected term represents the period that our share-based awards are expected to be outstanding and is determined by evaluating past experience and using other estimating tools.

Expected Volatility. Expected volatility represents the volatility in our stock price expected over the expected term of the 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 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 government 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 is calculated as the difference between the fair market value of the stock on the date of grant, less the cost to acquire the shares, which is $0.0001 per share.

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 are currently subject to income taxes only in the United States but have been subject to income taxes in both the United States and the United Kingdom in previous years. 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 at December 31, 2012 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 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

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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 Standards 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 May 2011, the FASB issued ASU No. 2011-04, *Amendment to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04, updating ASC *Topic 820, Fair Value Measurement.* This guidance clarifies existing fair value guidance and expands disclosure requirements on, among other things, fair value measurements using Level 3 unobservable inputs. Level 3 unobservable inputs refer to prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity). This guidance requires disclosures of quantitative information about the inputs used in Level 3 valuations, the valuation process used, and the sensitivity of the fair value measurements to changes in unobservable inputs. Refer to Note 12 of the Consolidated Financial Statements, Fair Value of Financial Instruments for more description on fair value measurements using Level 3 unobservable inputs. This guidance is effective for interim and annual periods beginning after December 15, 2011, and is to be applied prospectively. Our adoption of this guidance effective January 1, 2012 resulted in additional disclosures in the notes to our consolidated financial statements, but did not have a material quantitative effect.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income*, updating ASC *Topic 220, Comprehensive Income.* Under the amended ASC *Topic 220* , an entity 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 guidance eliminates the option to present other comprehensive income and its components in the Statement of Stockholders Equity. This guidance does not change the components that are recognized in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Deferral of the Effective Date for the Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05,* updating ASC *Topic 220, Comprehensive Income.* This guidance defers changes in ASU 2011-05 that relate to the presentation of reclassification adjustments. The guidance in ASU 2011-05 and ASU 2011-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and is to be applied retrospectively. The Company conformed its presentation which did not have a material impact on the presentation of the consolidated financial statements.

In February 2013, the FASB issued ASU 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* The amendment of this update requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. generally accepted accounting principles (GAAP) to be reclassified in its entirety to net income. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP that provide additional detail about those amounts. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. The adoption of the guidance is not expected to have an impact on the Company s consolidated financial statements and is not expected to have an impact on the Company s future operating results.

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Results of Operations 2012 compared to 2011

	December 31,			
	2012	2011	$ Change	% Change
Revenue	$ 20,469,000	$ 5,009,000	$ 15,460,000	309%

The increase in revenue for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily related to the increase in consumable (reagent and test cartridge) revenues. Consumable revenue increased approximately $15,216,000, or 346%, to approximately $19,619,000 for the year ended December 31, 2012 from approximately $4,403,000 in 2011. This increase in reagent revenue was primarily driven by an increase in the test offerings available on our XT-8 instrument and a 78% increase in the number of our installed base of analyzers to 297 at December 31, 2012, from 167 analyzer placements as of December 31, 2011. Also, our average annuity per analyzer increased from approximately $51,000 per analyzer per year at December 31, 2011 to approximately $143,000 per analyzer per year at December 31, 2012. Pricing changes were not a material cause of our significant increase in revenue. The increase was not attributable to any one assay; however, our pharmacogenetics and infectious disease assay revenue increased significantly more than our other assay panels. In addition to the increase in reagent (consumables) revenue, higher instrument sales during the year ended December 31, 2012 resulted in an additional $312,000 of revenue over 2011. We anticipate that our XT-8 consumable and instrument revenues will continue to grow, however, we expect to experience increased revenue growth rates after we introduce our NexGen system and its related tests.

	December 31,			
	2012	2011	$ Change	% Change
Cost of Sales	$ 11,640,000	$ 6,206,000	$ 5,434,000	88%
Gross Profit (Loss)	$ 8,829,000	$ (1,197,000)	$ 10,026,000	838%

The increase in cost of sales for the year ended December 31, 2012 compared to the year ended December 31, 2011 was primarily related to the increase in consumable (reagent and test cartridge) revenues. The improvement to gross profit of $10,026,000 was primarily due to increased sales volumes and manufacturing efficiencies. The increase in volume, particularly in the fourth quarter of 2012 with the addition of our Respiratory Viral Panel and 3A4/3A5 tests, allowed us to increase absorption of our fixed manufacturing costs of approximately $2,365,000, of our Carlsbad facility, supporting the higher volumes by increasing shift lengths and more efficient usage of existing manufacturing facilities and equipment. We also continue to realize improved manufacturing efficiencies by driving process improvements related to larger batch sizes, which has resulted in substantially improved manufacturing yields.

	December 31,			
	2012	2011	$ Change	% Change
Sales and Marketing	$ 6,378,000	$ 4,969,000	$ 1,409,000	28%

The increase of $1,409,000 in sales and marketing expense for the year ended December 31, 2012, compared to the year ended December 31, 2011, was primarily driven by an increase in salary expense of $1,449,000, associated with our commitment to increase and improve our domestic commercial organization. The increase reflected the addition of approximately 10 headcount (four in marketing and six in sales force).

	December 31,			
	2012	2011	$ Change	% Change
General and Administrative	$ 10,806,000	$ 8,960,000	$ 1,846,000	21%

General and administrative expense was $10,806,000 for the year ended December 31, 2012 compared to $8,960,000 for the same period last year. The increase of approximately $1,846,000 was due primarily to an increase of twelve headcount representing $807,000, building lease expenses of $388,000, expenses associated

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with audit fees and ongoing liquidation activities related to Osmetech of $189,000, outside services related to internal control testing and material weakness remediation of $176,000, and outside services to support our human resources group of $118,000.

	December 31,			
	2012	2011	$ Change	% Change
Research and Development	$ 13,536,000	$ 8,737,000	$ 4,799,000	55%

The increase in research and development expense of $4,799,000 for the year ended December 31, 2012, compared to the year ended December 31, 2011, was primarily due to an increase in costs associated with the development of our NexGen system of $4,667,000. In addition, the increase was due to the creation of new software development and product technical support departments to improve our product reliability and enhance our product effectiveness of $1,165,000. These increases were partially offset by lower assay development expenses of $740,000 in 2012, since there were no clinical trials ongoing during the year. Clinical trial costs tend to fluctuate depending on the timing of assay approvals through the FDA and requirements by the FDA for additional information related to a specific assay.

	December 31,			
	2012	2011	$ Change	% Change
Other Expense	$ (64,000)	$ (55,000)	$ (9,000)	(16%)

Other expense represents non-operating revenue and expenses, earnings on cash, cash equivalents and restricted cash and interest expense related to debt, capital leases and foreign exchange gain. The change in other (expense)/income for the year ended December 31, 2012, compared to the year ended December 31, 2011, was due primarily to an increase in interest expense related to our equipment term loan and capital leases.

	December 31,			
	2012	2011	$ Change	% Change
Provision for Income Taxes	$ (148,000)	$ (52,000)	$ (96,000)	(185%)

Due to net losses incurred, we have only recorded tax provisions related to United Kingdom tax interest on uncertain tax positions and minimum tax payments and refunds.

Results of Operations 2011 compared to 2010

	December 31,			
	2011	2010	$ Change	% Change
Revenue	$ 5,009,000	$ 2,564,000	$ 2,445,000	95%

Product sales increased $2,359,000, or 101%, to $4,700,000 for the year ended December 31, 2011 compared to $2,341,000 for the year ended December 31, 2010, which was primarily driven by increased reagent revenues as well as system sales as our installed base of systems placed with customers expanded from 2010. License and other revenue increased $86,000 to $309,000, or 39%, for the year ended December 31, 2011 compared to the year ended December 31, 2010. The effects of inflation and price increases were not significant contributors to revenues for the years ended December 31, 2011 and 2010.

	December 31,			
	2011	2010	$ Change	% Change
Cost of Sales	$ 6,206,000	$ 3,979,000	$ 2,227,000	56%
Gross Loss	$ 1,197,000	$ 1,415,000	$ (218,000)	(15%)

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The increase in cost of sales for the twelve months ended December 31, 2011 compared to the twelve months ended December 31, 2010 was due to higher cost of goods sold expense of $910,000 directly related to the increase in reagent sales, an inventory write down of $1,002,000 recorded during the year, and higher labor costs of $358,000 related to relocating our manufacturing facilities from Pasadena to our Carlsbad location in 2011. The inventory charge reflected the write-off of several assay production lots that did not meet our quality standards and other one-time expenses related to relocating our manufacturing facility from Pasadena, California to the current Carlsbad, California location, which was completed in June 2011.

The decrease in our gross loss resulted primarily from higher sales volumes directly related to our increase in revenues and the effect of the one-time charges to cost of sales. Our gross loss improved as manufacturing efficiencies were realized due to increased production volumes in 2011 compared to 2010.

	December 31,			
	2011	2010	$ Change	% Change
Sales and Marketing	$ 4,969,000	$ 4,555,000	$ 414,000	9%

The increase in sales and marketing expense for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was primarily caused by higher commission payment of $388,000.

	December 31,			
	2011	2010	$ Change	% Change
General and Administrative	$ 8,960,000	$ 7,415,000	$ 1,545,000	21%

General and administrative expense increased for the twelve months ended December 31, 2011 as compared to the twelve months ended December 31, 2010 due to increases in consulting, outside services and professional services, including fees of $1,874,000 for corporate restructuring, testing required under the Sarbanes-Oxley Act and consulting services related to business and process improvements. These increases were partially offset by the reduction of expenses in relocation ($122,000) and reorganization ($278,000) at our United Kingdom and Pasadena, California operations to Carlsbad, California.

	December 31,			
	2011	2010	$ Change	% Change
Research and Development	$ 8,737,000	$ 6,646,000	$ 2,091,000	31%

The increase in research and development expense for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was due to additional costs incurred in 2011 for clinical trials for our Respiratory Viral Panel Test, higher payroll costs as we continued to develop additional test menu product offerings, and patent-related legal costs.

	December 31,			
	2011	2010	$ Change	% Change
Other (Expense) Income	$ (55,000)	$ 1,643,000	$ (1,698,000)	(103%)

Other (expense)/income represents non-operating revenue and expenses, earnings on cash, cash equivalents and investments, interest expense related to a loan payable and foreign currency gains or losses. The decrease in other (expense)/income for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was due primarily to recognizing the Therapeutic Discovery Credit in 2010. There was no

similar benefit for the year ended December 31, 2011.

	December 31,			
	2011	2010	$ Change	% Change
Provision for Income Taxes	$ (52,000)	$ (15,000)	$ (37,000)	(247%)

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Due to net losses incurred, we have only recorded tax provisions or benefits related to expected United Kingdom tax, interest on uncertain tax positions, minimum tax payments and refunds.

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock, borrowings and cash from operations. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At December 31, 2012, we had $48,828,000 of working capital, including $52,593,000 in cash, cash equivalents and restricted cash. Net cash used in operations decreased $2,971,000 to $16,243,000 for the year ended December 31, 2012 compared to $19,214,000 for the year ended December 31, 2011. Net cash used in investing activities decreased $4,964,000 to $2,146,000 for the year ended December 31, 2012 compared to $7,110,000 for the year ended December 31, 2011 due to the maturity of $5,000,000 in short-term investments. Net cash provided by financing activities increased $11,057,000 to $44,319,000 for the year ended December 31, 2012 compared to $33,262,000 for the year ended December 31, 2011, due primarily to the issuance of approximately 11.5 million shares of our common stock in June 2012 from which we derived $45,089,000 in net proceeds.

Cash Flows

The following table summarizes, for the periods indicated, selected items in our consolidated statements of cash flows:

	December 31,	
	2012	**2011**
Twelve months ended:		
Cash used in operating activities	$ (16,243,000)	$ (19,214,000)
Cash used in investing activities	(2,146,000)	(7,110,000)
Cash provided by financing activities	44,319,000	33,262,000
Effect of foreign exchange rate changes		53,000
Net increase in cash and cash equivalents	$ 25,930,000	$ 6,991,000

Cash flows used in operating activities

Net cash used in operating activities decreased $2,971,000 to $16,243,000 for the twelve months ended December 31, 2012, compared to $19,214,000 for the twelve months ended December 31, 2011. The decrease in cash used in operating activities was primarily due to our lower net loss of $1,867,000 for the twelve months ending December 31, 2012 compared to the prior year period and an increase in accrued compensation of $832,000.

Cash flows used in investing activities

Net cash used in investing activities decreased by $4,964,000 to $2,146,000 for the twelve months ended December 31, 2012, compared to net cash used in investing activities of $7,110,000 for the twelve months ended December 31, 2011. This decrease was primarily due to the maturity

of a short-term investment of $5,000,000. This was offset by an increased use of cash for plant, property and equipment of $2,100,000, which was mainly for purchases of instruments to be placed at customer sites and partly for tenant improvements of our existing and expanding facility. We used $1,343,000 to secure our term loan and letter of credit with First PacTrust Bankcorp and $1,000,000 to purchase preferred securities of our strategic partner, Advanced Liquid Logic, Inc.

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Cash flows provided by financing activities

Net cash provided by financing activities was $44,319,000 for the twelve months ended December 31, 2012, compared to net cash provided by financing activities of $33,262,000 for the twelve months ended December 31, 2011. During the second quarter of 2012, we issued approximately 11.5 million shares of our common stock netting $45,089,000 after offering costs. During the second quarter of 2011, we issued 8,125,440 shares of our common stock netting $31,679,000 after offering costs. During the first quarter of 2011, we also drew down a $2,000,000 term loan on our then existing credit facility with Square 1 Bank discussed in greater detail below. In 2012, we have not drawn down any loans and have repaid a substantial portion of our outstanding indebtedness. The entire remaining balance of our outstanding indebtedness is recorded as the current portion of long-term debt.

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. Although we believe, based on our current business plan, that we have sufficient capital to reach a positive cash flow position, the amount of additional capital we may need to raise in the future depends on many factors, including:

- the level of revenues and the rate of our revenue growth;
- the level of expenses required to expand our commercial (sales and marketing) activities;
- the level of research and development investment required to maintain our XT-8 system and develop our NexGen system and related test menu;
- our need to acquire or license complementary technologies;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments; and,
- changes in regulatory policies or laws that affect our operations.

We cannot be certain that additional capital will be available when needed or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in diagnostics companies or in the marketplace in general is limited due to then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire, on acceptable terms, or at all. In addition, 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 obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. 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.

In March 2010, we entered into a loan and security agreement with Square 1 Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $2.0 million and an equipment term loan in the amount of up to $2.0 million. In March 2011, we amended the loan and security agreement to increase the line of credit to $3.0 million and extend the original maturity date to July 2012.

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In September 2012, we terminated the Square 1 Bank loan and security agreement and entered into a new term loan with First PacTrust Bancorp, consisting of the following two loans which were secured with $1,343,000 of restricted cash at December 31, 2012.

1) We increased the letter of credit provided to our landlord of our Carlsbad, California location to $758,000 from the previous letter of credit of $500,000. The increase in the letter of credit was required by our landlord pursuant to our second and third amendments to the lease for our Carlsbad, California location, in connection with our lease of additional space at this facility.

2) We obtained a variable rate term loan from First PacTrust Bankcorp in the amount of $836,000 with an initial interest rate of 3.75% that expires in July 2013. This term loan replaced the Square 1 equipment loan of the same amount with an interest rate of 6.75%.

Pursuant to the terms of the First PacTrust Bankcorp business loan agreement, we are required to maintain restricted cash, honor certain representations and warranties (including, but not limited to, organization, financial information and taxes), affirmative covenants (including, but not limited to, financial records, insurance and environmental compliance and reports), negative covenants (including, but not limited to, indebtedness of liens, continuity of operations and loans, acquisitions and guaranties) and other provisions; however, we are not required to maintain liquidity ratios, restrictive covenants or other limitations, to which we were subject under the Square 1 Bank loan and security agreement.

Contractual Obligations

As of December 31, 2012, we had the following contractual obligations *(in thousands)*:

		Payments due by period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating lease obligations (1)	$ 9,598	$ 1,023	$ 3,252	$ 2,279	$ 3,044
Licensing payment obligation	6,175	1,860	4,139	176	
Loan repayment obligations	585	585			
Instrument purchase obligations	2,115	913	1,202		
Taxes	148	148			
Total obligations	$ 18,621	$ 4,529	$ 8,593	$ 2,455	$ 3,044

(1) We enter into operating 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 operating leases.

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, and the project totals approximately 160,000 rentable square feet. Our original monthly rental payments were approximately $48,000, subject to 3% annual increases. We originally paid a $55,000 security deposit under the terms of the lease and provided a $500,000 standby letter of credit as security for future rent.

In January 2012, we entered into a lease amendment for adjoining facility space for approximately an additional 22,000 square feet. We are utilizing the additional space to expand our manufacturing capabilities and for additional office and warehouse space. 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.

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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 payoff previous contracts for similar equipment leased from a different vendor.

In October 2010, we entered into a license agreement pursuant to which we were granted access to certain intellectual property rights. The agreement required minimum payments of 1.0 million in four equal installments over two years following its effective date and contains provisions for additional licensing fees of 1.25 million and additional royalties based on related product sales. The license terminates upon our election, termination of every patent and patent application licensed under the agreement, or the material breach of either party, in each case subject to the terms of the agreement.

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.

Tax Obligations

In addition to the table above, approximately $590,000 of unrecognized tax benefits, including $208,000 of accrued interest and penalties, have been recorded as liabilities and we are uncertain as to if or when such amounts may be settled.

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, except that we have provided a $758,000 standby letter of credit as security for future rent to our landlord in connection the lease of our Carlsbad, California facility, as discussed in greater detail above.

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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 short-term investments, 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, 2012, 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. Virtually all of our revenues are based in the United States. In 2010, we entered into a license agreement that requires payment in Euros, and a small portion of our expenses in the first quarter of 2010, relating to our corporate office, were transacted in British Pounds. We currently have no material operations outside of the United States, which significantly diminishes the extent of any foreign currency exchange risk we face.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

GenMark Diagnostics, Inc.

Carlsbad, California

We have audited the accompanying consolidated balance sheets of GenMark Diagnostics, Inc. and subsidiaries (the Company) (formerly Osmetech plc and subsidiaries) as of December 31, 2012 and 2011, and the related consolidated statements of comprehensive loss, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2012. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated 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, such consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2013, expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

San Diego, California

March 14, 2013

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GenMark Diagnostics, Inc.

Consolidated Balance Sheets

(In thousands, except par value)

	As of December 31, 2012	2011
Current assets		
Cash and cash equivalents	$ 51,250	$ 25,320
Short-term investments		5,000
Restricted cash	1,343	
Accounts receivable net of allowance of $30 and $98	3,190	1,098
Inventories	1,993	2,168
Other current assets	226	322
Total current assets	58,002	33,908
Property and equipment, net	7,074	2,836
Intangible assets, net	1,832	1,362
Other long-term assets	1,108	80
Total assets	$ 68,016	$ 38,186
Current liabilities		
Accounts payable	$ 2,445	$ 1,201
Accrued compensation	3,076	1,521
Current portion of loan payable	638	1,000
Other current liabilities	3,015	2,659
Total current liabilities	9,174	6,381
Long-term liabilities		
Loan payable, net of current portion	63	583
Other noncurrent liabilities	2,329	588
Total liabilities	11,566	7,552
Commitments and contingencies See note 6		
Stockholders equity		
Common stock, $0.0001 par value; 100,000 authorized; 32,753 and 20,478 shares issued and outstanding as of December 31, 2012 and December 31, 2011, respectively	3	2
Preferred stock, $0.0001 par value; 5,000 authorized, none issued		
Additional paid-in capital	247,449	199,531
Accumulated deficit	(190,566)	(168,463)
Accumulated other comprehensive loss	(436)	(436)
Total stockholders equity	56,450	30,634
Total liabilities and stockholders equity	$ 68,016	$ 38,186

The accompanying notes are an integral part of these consolidated financial statements.

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GenMark Diagnostics, Inc.

Consolidated Statements of Comprehensive Loss

(In thousands, except per share amounts)

	Year ended December 31,		
	2012	**2011**	**2010**
Revenue			
Product revenue	$ 20,211	$ 4,700	$ 2,341
License and other revenue	258	309	223
Total revenue	20,469	5,009	2,564
Cost of sales	11,640	6,206	3,979
Gross profit (loss)	8,829	(1,197)	(1,415)
Operating expenses			
Sales and marketing	6,378	4,969	4,555
General and administrative	10,806	8,960	7,415
Research and development	13,536	8,737	6,646
Total operating expenses	30,720	22,666	18,616
Loss from operations	(21,891)	(23,863)	(20,031)
Other (expense) income			
Foreign exchange gain (loss)	6	6	(1)
Interest (expense) income, net	(49)	(74)	
Therapeutic discovery credit			1,644
Other (expense) income, net	(21)	13	
Total other (expense) income	(64)	(55)	1,643
Loss before income taxes	(21,955)	(23,918)	(18,388)
Provision for income taxes	(148)	(52)	(15)
Net loss	$ (22,103)	$ (23,970)	$ (18,403)
Net loss per share, basic and diluted	(0.84)	(1.45)	(1.88)
Weighted average number of shares outstanding	26,215	16,572	9,797
Other comprehensive loss			
Net loss	$ (22,103)	$ (23,970)	$ (18,403)
Foreign currency translation adjustment		14	(35)
Comprehensive loss	$ (22,103)	$ (23,956)	$ (18,438)

The accompanying notes are an integral part of these consolidated financial statements.

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GenMark Diagnostics, Inc.

Consolidated Statements of Stockholders Equity

(In thousands)

	Ordinary Shares		Deferred Stock							
	Shares	Par value	Shares	Par value	Common Stock Shares	Par Value	Additional paid-in capital	Accumulated other compre-hensive loss	Accumulated deficit	Total
Balance Dec. 31, 2009	1,633,443	$ 2,574	689,478	$ 11,781		$	$ 127,475	$ (415)	$ (126,090)	$ 15,325
Share-based compensation related to share options							1,553			1,553
Exercise of share options	4,965	7								7
Reorganization	(1,638,408)	(2,581)	(689,478)	(11,781)	7,128	1	14,361			
Issuance of common stock, net of offering expenses					4,600		22,620			22,620
Foreign currency translation adjustment								(35)		(35)
Net loss									(18,403)	(18,403)
Balance Dec. 31, 2010		$		$	11,728	$ 1	$ 166,009	$ (450)	$ (144,493)	$ 21,067
Share-based compensation expense							1,872			1,872
Shares issued under stock-based compensation plans, net of cancellations					625		(28)			(28)
Issuance of common stock, net of offering expenses					8,125	1	31,678			31,679
Foreign currency translation adjustment								14		14
Net loss									(23,970)	(23,970)
Balance Dec. 31, 2011		$		$	20,478	$ 2	$ 199,531	$ (436)	$ (168,463)	$ 30,634
Issuance of stock in lieu of accrued bonuses					93		255			255
Share-based compensation expense							2,352			2,352
Shares issued under stock-based compensation plans, net of cancellations					682		223			223
Issuance of common stock, net of offering expenses					11,500	1	45,088			45,089
Net loss									(22,103)	(22,103)
Balance Dec. 31, 2012		$		$	32,753	$ 3	$ 247,449	$ (436)	$ (190,566)	$ 56,450

The accompanying notes are an integral part of these financial statements.

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GenMark Diagnostics, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net loss	$ (22,103)	$ (23,970)	$ (18,403)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,198	1,326	1,063
Share-based compensation	2,352	1,872	1,553
Bad debt provision	(24)		
Non-cash inventory adjustments	(482)	517	
Changes in operating assets and liabilities:			
Accounts receivable	(2,068)	(420)	(508)
Inventories	(880)	(1,742)	(651)
Other current assets	68	1,846	(1,404)
Accounts payable	728	378	(1,058)
Accrued compensation	1,811	979	547
Other liabilities	1,397		
Net cash used in operating activities	(16,243)	(19,214)	(18,861)
Cash flows from investing activities			
Restricted cash	(1,343)		
Purchase of preferred securities	(1,000)		
Payments for intellectual property licenses	(1,327)	(734)	
Purchases of property and equipment	(3,476)	(1,376)	(1,860)
Short-term investments	5,000	(5,000)	
Net cash used in investing activities	(2,146)	(7,110)	(1,860)
Cash flows from financing activities			
Proceeds from issuance of common stock	48,300	34,533	27,600
Costs incurred in conjunction with public offering	(3,211)	(2,854)	(4,991)
Proceeds from borrowings	991	2,000	
Principal repayment of borrowings	(1,984)	(417)	5
Proceeds from stock exercises	223		
Net cash provided by financing activities	44,319	33,262	22,614
Effect of foreign exchange rate changes		53	(47)
Net increase in cash and cash equivalents	25,930	6,991	1,846
Cash and cash equivalents at beginning of year	25,320	18,329	16,483
Cash and cash equivalents at end of year	$ 51,250	$ 25,320	$ 18,329
Non-cash investing and financing activities:			
Property and equipment purchased with capital lease	$ 109	$	$
Transfer of systems from property and equipment into inventory	$ 223	$ 46	$ 109

Property and equipment costs incurred but not paid included in accounts payable	$ 592	$ 76	$ 276
Leasehold improvements related to lease incentives	$ 1,359	$	$
Intellectual property acquisition included in accrued expenses	$	$	$ 1,389
Reclassification of deposits on systems in other current assets and inventory to property and equipment	$	$	$ 289
IPO costs incurred but not paid	$	$	$ 103
Supplemental cash flow information:			
Cash paid for interest	$ 90	$ 95	$
Cash received for interest	$ 42	$ 21	$ 25
Cash received for income taxes, net	$	$ 3	$ 5
Cash paid for income taxes	$ 91	$	$

The accompanying notes are an integral part of these consolidated financial statements.

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GenMark Diagnostics, Inc.

Notes to Consolidated Financial Statements

1. Organization and basis of presentation

GenMark Diagnostics, Inc., the Company or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware 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.

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, meaning:

i. assets and liabilities were carried over at their respective carrying values;

ii. common stock was carried over at the nominal value of the shares issued by GenMark;

iii. additional paid-in capital represented the difference between the nominal value of the shares issued by GenMark, and the total of the additional paid-in capital and nominal value of Osmetech s shares cancelled pursuant to the reorganization; and

iv. the accumulated deficit represented the aggregate of the accumulated deficit of Osmetech and 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 were exchanged for options and warrants exercisable for the common stock of the Company.

In these consolidated financial statements, the Company means Osmetech when referring to periods prior to the IPO.

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 $190.6 million at December 31, 2012. Cash, cash equivalents and restricted cash at December 31, 2012 was $52.6 million. 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.

Management expects operating losses to continue through the foreseeable future until the Company has expanded its product offering and consequently increased its product revenues to an extent to cover the fixed cost base of the business. The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of credit facilities, that the Company has sufficient capital to fund its operations for at least the next twelve months.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles and applicable regulations of the Securities and Exchange Commission, or the SEC. The Company s operating results for the year ended December 31, 2012 are not necessarily indicative of the results that may be expected for any future periods.

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The Company operates in one reportable and operating segment, which is the development and commercialization of molecular tests based on its proprietary eSensor® detection technology. Substantially all of the Company s operations and assets are in the United States of America.

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.

Corporate Reorganization

During the quarter ended June 30, 2011, the Company underwent a corporate reorganization intended to simplify its U.S. entity structure. As part of the reorganization, Osmetech Technologies, Inc. merged into Clinical Micro Sensors, Inc., or CMS, with CMS surviving. Additionally, Osmetech plc converted to a U.K. limited company for U.K. legal and tax purposes, and made an entity classification election to be treated as an entity disregarded from GenMark Diagnostics, Inc. for U.S. federal income tax purposes. The reorganization did not trigger any material U.S. federal or U.K. income tax expense. Additionally, the post-reorganization structure allowed GenMark Diagnostics, Inc. to elect to file a consolidated U.S. federal income tax return with its remaining U.S. subsidiaries, CMS and Osmetech, Inc. In September 2012, the Company filed to liquidate Osmetech plc and expects the liquidation to be completed during 2013.

2. Summary of significant accounting policies

Cash and Cash Equivalents and Short-Term Investments

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. Short-term investments consist of certificates of deposits that mature in greater than three months, but less than one year from the date of purchase. The carrying amounts reported in the balance sheets for cash, cash equivalents and short-term investments, if any, are stated at cost which approximates their fair market value.

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and includes $1,343,000 at December 31, 2012 held as security for the Company s term loan and letter of credit with First PacTrust Bankcorp.

Fair Value of Financial Instruments

The Company determines the fair value of its assets and liabilities based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the

use of unobservable inputs. 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.

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The carrying amounts of financial instruments such as cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, and accrued liabilities, excluding acquisition related contingent consideration 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 upon specific identification of accounts at risk plus a general reserve for unknown items based upon the Company s historical experience.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market 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 market, if applicable. 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 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 (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.

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 five to 10 years. Amortization of licenses typically begins upon the Company obtaining access to the licensed technology and is recorded in cost of sales.

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

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its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows. The Company did not recognize any impairment charges during the years ended December 31, 2012, 2011 and 2010.

Use of Estimates

The preparation of 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, certain accrued liabilities related to the Company s former facilities, warranty liabilities, tax valuation accounts and share-based compensation. Actual results could differ from those estimates.

Segment Information

The Company currently operates in one business segment which encompasses the development, manufacturing, marketing, sales and support of instruments and molecular tests based on its proprietary eSensor® detection technology. Although the Company offers multiple tests for its XT-8 system, and is developing new tests for its XT-8 system, the Company does not operate its business in operating segments. The Company determined, in accordance with Financial Accounting Standards Board, (FASB), Accounting Standards Codification (ASC) Topic 280, Segment Reporting, to operate as one operating segment. The Company s Chief Operating Decision Maker (CODM) is its Chief Executive Officer and he reviews revenue at the business group level and manufacturing, operating income and expenses, and net income at the Company wide level to allocate resources and assess the Company s overall performance. The Company s business shares a centralized support function, including finance, human resources, legal, and corporate marketing, all of which report directly to the CODM. Accordingly, decisions regarding the Company s overall operating performance and allocation of Company resources are assessed on a consolidated basis.

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 the system 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 or reagent rental agreement expirations. 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 a system is installed on the premises of a pre-qualified customer for the purpose of allowing the customer to evaluate the system 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.

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Revenues related to royalties received from licenses are recognized evenly over the contractual period to which the license relates. Services provided are recognized using the proportional performance method of accounting.

In those cases where the Company bills shipping and handling costs to customers, the amounts billed are classified as 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, 2012 and 2011 is as follows (in thousands):

	2012	2011	2010
Beginning balance	$ 92	$ 25	$ 0
Warranty expenses incurred	(305)	(135)	
Provisions	430	202	25
Ending balance	$ 217	$ 92	$ 25

Research and Development Costs

Research and development expenses primarily include expenses related to the development of the Company s XT-8 system test menu and costs associated with the development of the Company s NexGen system. These expenses also include clinical study expenses incurred in the process of preparing for FDA clearance for these systems and test cartridges and quality assurance costs. The expenses primarily consist of salaries, benefits, share-based compensation costs, outside design and consulting services, laboratory supplies, intellectual property protection, contract research organization expenses, clinical study supplies and facility costs.

The Company expenses all research and development costs in the periods in which they are incurred.

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

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the amounts and probabilities of the outcomes that could be realized upon settlement using the facts, circumstances and information available at the reporting date.

Share-Based Compensation

The Company recognizes share-based compensation expense related to share options and restricted stock awards, or RSAs, granted to employees and directors in exchange for services. The compensation expense is based on the fair value of the share-based compensation utilizing various assumptions regarding the underlying attributes of the options and shares.

The estimated fair value of options 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 share-based compensation expense is recorded in costs of sales, sales and marketing, research and development and general and administrative expenses based on the employee s respective function. The expense is derived from the Black-Scholes Option Pricing Model that uses several judgment-based variables to calculate the expense. The inputs include the expected term of the option or warrant, the expected volatility and other factors.

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 is calculated as the difference between the fair market value of the stock on the date of grant, less the cost to acquire the shares, as further adjusted to reflect a forfeiture rate.

Foreign Currency Translation

During 2010, the Company changed its functional currency from the British Pound to the U.S. Dollar. Prior to this change, monetary assets and liabilities of the Company s entities outside of the U.S. were translated into U.S. dollars based on foreign currency exchange rates in effect at the end of each period, and revenues and expenses were 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 were recorded in accumulated other comprehensive loss in the consolidated balance sheets.

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 $6,000, $6,000 and ($1,000) for the years ended December 31, 2012, 2011 and 2010, respectively, and relate primarily to transactions denominated in U.S. dollars which were undertaken by Osmetech and to satisfy payment obligations denominated in Euros under an intellectual property license.

Net Loss per Common Share

Basic net loss per share is computed by dividing loss available to shareholders of our common stock (the numerator) by the weighted average number of shares of our 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

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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. As the Company had a net loss in each of the periods presented, basic and diluted net loss per share are the same.

The computations of diluted net loss per share for the years ended December 31, 2012, 2011 and 2010 did not include the effects of the following options and warrants to acquire stock which were outstanding as of the end of each year as the inclusion of these securities would have been anti-dilutive (in thousands).

	Year Ended December 31,		
	2012	2011	2010
Share options	1,539	1,599	1,108
Warrants		88	88
Restricted stock-unvested, issued and held in escrow	966	403	
Restricted stock-vested, not issued or outstanding			204
	2,505	2,090	1,400

Concentration of Risk

The Company had sales to individual customers representing greater than 10% of the total revenues for the years ended December 31, 2012, 2011 and 2010, as follows:

	Year Ended December 31,		
	2012	2011	2010
Natural Molecular	58%	20%	
BioReference			12%
Companion Dx	10%		

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 loss and foreign currency translation. Comprehensive loss for the year ended December 31, 2012 and 2011 was $22.1 million and $24.0 million, respectively.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards 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 May 2011, the FASB issued ASU No. 2011-04, *Amendment to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, or ASU 2011-04, updating ASC *Topic 820, Fair Value Measurement.* This guidance clarifies existing fair value guidance and expands disclosure requirements on, among other things, fair value measurements using Level 3 unobservable inputs. Level 3 unobservable inputs refer to prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity). This guidance requires disclosures of quantitative information about the inputs used in Level 3 valuations, the valuation process used, and the sensitivity of the fair value measurements to changes in unobservable inputs. Refer to Note 12 of

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the Consolidated Financial Statements, Fair Value of Financial Instruments for more description on fair value measurements using Level 3 unobservable inputs. This guidance is effective for interim and annual periods beginning after December 15, 2011, and is to be applied prospectively. Our adoption of this guidance effective January 1, 2012 resulted in additional disclosures in the notes to our consolidated financial statements, but did not have a material quantitative effect.

In June 2011, the FASB issued ASU 2011-05, *Presentation of Comprehensive Income*, updating ASC *Topic 220, Comprehensive Income.* Under the amended ASC *Topic 220* , an entity 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 guidance eliminates the option to present other comprehensive income and its components in the Statement of Stockholders Equity. This guidance does not change the components that are recognized in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Deferral of the Effective Date for the Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05,* updating ASC *Topic 220, Comprehensive Income.* This guidance defers changes in ASU 2011-05 that relate to the presentation of reclassification adjustments. The guidance in ASU 2011-05 and ASU 2011-12 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, and is to be applied retrospectively. The Company conformed its presentation which did not have a material impact on the presentation of the consolidated financial statements.

In February 2013, the FASB issued ASU 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* The amendment of this update requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. generally accepted accounting principles (GAAP) to be reclassified in its entirety to net income. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP that provide additional detail about those amounts. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. The adoption of the guidance is not expected to have an impact on the Company s consolidated financial statements and is not expected to have an impact on the Company s future operating results.

3. Intangible assets

Intangible assets as of December 31, 2012 and 2011, respectively, comprise the following (in thousands):

	December 31, 2012			December 31, 2011		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$ 3,144	$ (1,312)	$ 1,832	$ 2,474	$ (1,112)	$ 1,362

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Licenses have a weighted average remaining amortization period of 8.1 years as of December 31, 2012. Amortization expense for intangible assets amounted to $200,000, $98,000 and $68,000 for the years ended December 31, 2012, 2011 and 2010, respectively. Estimated future amortization expense for these licenses is as follows (in thousands):

Years Ending December 31,	
2013	$ 226
2014	226
2015	226
2016	223
2017	219
Thereafter	712
Total	$ 1,832

4. Share-based compensation

On June 3, 2010, the Company exchanged all of the outstanding options under the Osmetech 2003 U.S. Equity Compensation Plan for options under the Company s 2010 Equity Incentive Plan, or the 2010 Plan. The options were exchanged using an exchange ratio of 230 options to purchase shares of Osmetech to one share of the Company. The exchange was accounted for as a modification of the share-based payment arrangement. There was no additional compensation cost recorded related to the exchange as there was no change in the economic value of the options exchanged.

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, 2012, there were 8,687 shares available for future grant of awards under the Plan. Restricted stock grants reduce the number of shares available for grant under the 2010 Plan.

The following table summarizes stock option activity during the year ended December 31, 2012:

	Number of shares	Weighted average exercise price (translated to dollars)
Outstanding at December 31, 2011	1,598,894	$ 5.38
Granted	410,397	$ 5.34
Exercised	(63,667)	$ 4.64
Cancelled	(406,911)	$ 5.34

Outstanding at December 31, 2012	1,538,713	$	5.42
Exercisable at December 31, 2012	810,202	$	5.65

The weighted average fair value of options granted during the years ended December 31, 2012, 2011 and 2010 was $3.80, $2.86 and $5.29 per share, respectively. The intrinsic value of options exercised during the year ended December 31, 2012 was $277,443. The intrinsic value of options exercised during the year ended December 31, 2010 was $136,157. No options were exercised in the year ended December 31, 2011. As of

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December 31, 2012, there were 1,538,713 options outstanding, which had a remaining weighted average contractual term of 8.11 years and an aggregate intrinsic value of $5,471,192. Options that are exercisable as of December 31, 2012 have a remaining weighted average contractual term of 7.57 years, and an aggregate intrinsic value of $2,721,086.

Valuation of Share-Based Awards The Black-Scholes Option Pricing Model was used for estimating the grant date fair value of stock options granted during the years ended December 31, 2012, 2011 and 2010, respectively, with the following assumptions:

In accordance with ASC 718, the Company evaluates the option award assumptions used in the Black-Scholes model at each grant date using a consistent methodology for computing expected volatility, expected term and risk-free rate of return. Calculation of expected volatility is based on historical volatility, along with a comparison of comparable volatility in the Company s industry. The expected term is calculated using the vesting period of the award using the simplified method. The estimate of the risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company has never paid cash dividends and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield. The assumptions used are summarized in the following table:

	Year Ended December 31,		
	2012	2011	2010
Expected volatility (%)	75.00	70.00	70.00
Expected life (years)	5.92	6.07	5.91
Risk free rate (%)	0.97	2.30	2.10
Expected dividend yield (%)			

As part of the requirements of ASC 718, 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 performance 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.

Share Warrants During 2009, the Company issued warrants to purchase 88,317 of Osmetech s ordinary shares with an exercise price of £6.90 per share to a director for services to the Company in connection with the share offering completed in 2009. Pursuant to the terms of the warrant, this warrant was converted in connection with the Company s reorganization into a warrant to purchase 88,317 shares of the Company s common stock at an exercise price of $9.98. These warrants were fully vested and exercisable upon issue, and expired unexercised on June 30, 2012.

The Company s restricted stock activity for the year ended December 31, 2012 is as follows:

Restricted Stock Awards	Number of shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2011	403,062	$ 4.22
Granted	926,082	$ 4.82
Vested	(148,120)	$ 4.89
Cancelled or expired	(215,313)	$ 4.24

Non-vested at December 31, 2012	965,711	$	4.68

As of December 31, 2012, there was $3,221,000 of unrecognized compensation cost related to restricted stock awards. That cost is expected to be recognized over a weighted average-period of 1.38 years. The total fair

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value of restricted stock that vested during the year ended December 31, 2012, 2011 and 2010 was $724,000, $948,000 and $15,000, respectively.

Restricted stock awards 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 agreement. During the year ended December 31, 2012, the Company awarded 926,082 shares of restricted stock, which had a fair value at the date of grant ranging from $4.14 to $9.50 per share. During the year ended December 31, 2011, the Company awarded 449,289 shares of restricted stock, which had a fair value at the date of grant ranging from $3.95 to $5.85 per share. During the year ended December 31, 2010, the Company awarded 204,115 shares of restricted stock, which had a fair value at the date of grant ranging from $4.03 to $4.46 per share. Restricted stock compensation is charged to expense over the restriction period and amounted to $1,221,500, $911,000 and $247,000 in 2012, 2011 and 2010, respectively.

There was no share-based compensation costs capitalized into assets as of December 31, 2012.

Share-Based Compensation Share-based compensation was recognized in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Cost of sales	$ 125	$ 41	$ 19
Sales and marketing	558	297	261
Research and development	509	409	162
General and administrative	1,160	1,125	1,111
	$ 2,352	$ 1,872	$ 1,553

No share-based compensation was capitalized during the periods presented, and there was no unrecognized tax benefit related to share-based compensation for the years ended December 31, 2012, 2011 and 2010, respectively. At December 31, 2012, the estimated total remaining unamortized compensation expense, net of forfeitures, associated with share-based awards was approximately $2,050,000, which is expected to be recognized over a weighted-average period of 1.33 years.

5. Income Taxes

The components of loss before income taxes for the years ended December 31, 2012, 2011, and 2010, respectively, were as follows (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Domestic (U.S. Entities)	$ (21,955)	$ (23,918)	$ (18,388)
Foreign (non-U.S. Entities)			

	$ (21,955)	$ (23,918)	$ (18,388)

The components of income tax expense for continuing operations are as follows for the years ended December 31, 2012, 2011, and 2010, respectively (in thousands):

	2012	2011	2010
Current expense:			
U.S. provision	$	$	$
State	103	20	15
Foreign (non-U.S. entities)	45	32	
Total current expense	$ 148	$ 52	$ 15

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The components of net deferred income taxes consist of the following for the years ended December 31, 2012 and 2011, respectively (in thousands):

	2012	2011
Deferred income tax assets (liabilities):		
Compensation accruals	$ 1,241	$ 1,055
Accruals and reserves	1,139	634
State tax provision	9	11
Federal benefit of state UTP	168	174
UNICAP	1,033	1,559
Intangible Assets	834	867
NOL and credits	23,856	15,352
Subtotal: Deferred Tax Assets	28,280	19,652
Depreciation	(632)	(70)
Valuation allowance	(27,648)	(19,582)
Net deferred income taxes	$	$

A reconciliation of income tax (expense) / benefit for continuing operations to the amount computed by applying the statutory federal income tax rate (the federal rate has been utilized as the Company s main operation are taxed at the federal rate) to the loss from continuing operations is summarized for the years ended December 31, 2012, 2011, and 2010, respectively, as follows:

	2012	2011	2010
U.S. Federal statutory income tax rate	34.0%	34.0%	34.0%
Permanent differences	(0.9%)	(0.7%)	0.4%
State taxes	5.3%	(0.2%)	(0.1%)
Effect of non-U.S. operations	(0.2%)	(0.1%)	0.0%
Section 382 limitation on NOLs	0.0%	(4.3%)	0.0%
Other	(0.2%)	(1.8%)	0.0%
Valuation allowance	(38.9%)	(27.1%)	(34.4%)
Total tax provision	(0.9%)	(0.2%)	(0.1%)

The Company had federal net operating loss (NOL) carryforwards available of approximately $63.7 million and $42.0 million as of December 31, 2012 and 2011, respectively, after consideration of limitations under Section 382 of the Internal Revenue Code, or Section 382, as further described below. Additionally, the Company had state NOL carryforwards available of $49.2 million and $26.4 million as of December 31, 2012 and 2011, respectively. These may be used to offset future taxable income and will expire in varying amounts through 2032. The Company also has non-U.S. NOL carryforwards of $30.4 million. Because the Company restructured its operations during 2011, the non-U.S. net operating losses and other deferred tax assets have been removed from the Company s table of deferred income taxes above.

Of the $63.7 million and $49.2 million of federal and state NOL carryforwards at December 31, 2012, $0.6 million 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 our 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, 2012. As a result of this assessment, the Company determined that it experienced multiple ownership changes through 2011 which will limit the future utilization of NOL carryforwards and that the Company may have experienced an ownership change during 2012. The Company has determined that if an ownership change did occur during 2012 that the NOL limitation would not be any more restrictive than prior

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ownership changes. Accordingly, U.S. federal NOLs of approximately $57.5 million are expected to expire due to limitations under Section 382 and, as such, have not been reflected in the NOL carryforward above. 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, 2012. Such objective evidence limits the ability to consider other subjective evidence such as our projections for future growth. Based on this evaluation, as of December 31, 2012, a valuation allowance of $27.6 million has been recorded in order to measure only the portion of the deferred tax asset that more likely than not will be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence such as estimates of future taxable income during carryforward periods and our projections for growth.

The Company applies the provisions of ASC 740, Income Taxes (previously reported as Interpretation No. 48 Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109), which contains a 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.

Upon adoption of ASC 740 on January 1, 2007, the Company did not have any unrecognized tax benefits. A reconciliation of the beginning and ending amount of unrecognized tax benefits, exclusive of accrued interest, for the years ended December 31, 2012, 2011 and 2010, respectively, is as follows (in thousands):

	2012	2011	2010
Balance at January 1	$ 382	$ 382	$ 382
Additions based on tax positions related to the current year			
Additions for tax positions of prior years			
Reductions for tax positions of prior years			
Lapse of statute			
Settlements			
Balance at December 31	$ 382	$ 382	$ 382

At December 31, 2012 and December 31, 2011, the Company classified $590,000 and $509,000, respectively, of total unrecognized tax benefits, which includes accrued interest and penalties of $208,000 and $127,000 for 2012 and 2011, respectively, as a component of other long-term liabilities. This represents the amount of unrecognized tax benefits that would, if recognized, reduce the Company s effective income tax rate in any future periods. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 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 Kingdom, the United States and various states jurisdictions. As of December 31, 2012, the Company s tax years after 2008 are subject to examination by the

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United Kingdom tax authorities. Except for net operating losses generated in prior years carrying forward to the current year, as of December 31, 2012, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2007.

6. Commitments and contingencies

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.

Leases:

The Company has operating lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged were $1,323,000, $774,000 and $959,000 for the years ended December 31, 2012, 2011, and 2010, respectively. Pursuant to the Company s lease agreements, a portion of the monthly rental has been deferred. The balance deferred at December 31, 2012 and 2011 was $1,820,000 and $212,000, respectively. During the year ended December 31, 2012, the Company recorded $1,359,000 to the deferred rent balance in connection with certain tenant improvements made related to the Company s occupancy of additional space at its Carlsbad, CA facility.

Annual future minimum obligations for operating leases as of December 31, 2012 are as follows (in thousands):

Years Ending December 31,	Operating leases
2013	$ 1,023
2014	1,052
2015	1,084
2016	1,116
2017	1,123
Thereafter	4,199
Total minimum lease payments	$ 9,597

Licensing Agreements:

In October 2010, the Company entered into an intellectual property license agreement which required minimum payments of 1.0 million in four equal installments over two years and contains provisions for additional licensing fees of 1.25 million and additional royalty payments based on related product sales. The license terminates at the Company s election, termination of every patent and patent application licensed under the agreement, or the material breach of the agreement by either party, subject in each case to the terms of the agreement.

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. In addition, 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.

In July 2012, the Company entered into a Development Collaboration and License Agreement with Advanced Liquid Logic, Inc., or ALL. Under the terms of the agreement, the Company established a

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collaborative program with ALL to develop in-vitro diagnostic products incorporating ALL s proprietary electro-wetting technology in conjunction with our 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 provides that the Company would, upon the occurrence of certain events, be obligated to pay ALL a royalty consisting of a low- to mid-single digit percent of net sales of designated licensed products containing ALL components which are manufactured by the Company or are otherwise not manufactured and supplied by ALL. The Company purchased $1,000,000 in preferred stock recorded as an Intangible Asset on the Company s balance sheet of a collaborative development and licensing partner and reported the amount in the accompanying consolidated balance sheets as an other long-term asset.

7. Inventories

Inventory on hand as of December 31, 2012 and December 31, 2011 was comprised of the following (in thousands):

	2012	2011
Raw materials	$ 516	$ 1,012
Work-in-process	925	706
Finished goods	552	450
	$ 1,993	$ 2,168

8. Property and equipment, net

Property and equipment was comprised of the following as of December 31, 2012 and 2011 (in thousands):

	2012	2011
Property and equipment at cost:		
Plant and machinery	$ 3,059	$ 2,539
Instruments	5,795	3,918
Office equipment	1,047	848
Leasehold improvements	2,973	583
Total property and equipment at cost	12,874	7,888
Less accumulated depreciation	(5,800)	(5,052)
Net property and equipment	$ 7,074	$ 2,836

Depreciation expense on property and equipment amounted to $998,000, $1,228,000 and $995,000 for the years ended December 31, 2012, 2011 and 2010, respectively.

9. Loan payable and line of credit

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to which the Company obtained a credit facility consisting of a revolving line of credit in the amount of up to $2.0 million and an equipment term loan in the amount of up to $2.0 million. In March 2011, the Company amended the loan and security agreement to increase the line of credit to $3.0 million and extend the original maturity date to July 2012.

In September 2012, the Company terminated the Square 1 Bank loan and security agreement and entered into a new term loan with First PacTrust Bancorp, consisting of the following two loans which were secured with $1,343,000 of restricted cash at December 31, 2012.

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1) The Company increased the letter of credit provided to its landlord of its Carlsbad, California location to $758,000 from the previous letter of credit of $500,000. The increase in the letter of credit was required by the Company s landlord pursuant to its second and third amendments to the lease for its Carlsbad, California location, in connection with the Company s lease of additional space at this facility.

2) The Company obtained a variable rate term loan from First PacTrust Bankcorp in the amount of $836,000 with an initial interest rate of 3.75% that expires in July 2013. This term loan replaced the Square 1 equipment loan of the same amount with an interest rate of 6.75%. At December 31, 2012, the outstanding balance on the term loan was $585,000.

Pursuant to the terms of the First PacTrust Bankcorp business loan agreement, the Company is required to maintain restricted cash, honor certain representations and warranties (including, but not limited to, organization, financial information and taxes), affirmative covenants (including, but not limited to, financial records, insurance and environmental compliance and reports), negative covenants (including, but not limited to, indebtedness of liens, continuity of operations and loans, acquisitions and guaranties) and other provisions; however, the Company is not required to maintain liquidity ratios, restrictive covenants or other limitations, to which it was subject under the Square 1 Bank loan and security agreement.

10. 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.

11. Other current assets and liabilities and other noncurrent liabilities consisted of the following as of December 31, 2012 and 2011 (in thousands):

	2012	2011
Other current assets		
Deposits and prepaid expenses	226	322
Total	$ 226	$ 322
Other long-term assets		
Deposit	$ 108	$ 80
Investment	$ 1,000	
Total	$ 1,108	$ 80
Other current liabilities		
Accrued professional fees	$ 229	$ 532
Deferred rental liabilities	95	167
Accrued warranties	217	92
Accrued royalties	472	103
Note payment received that must be refunded		345
Accrued intellectual property licenses		648
Accrued expenses	1,817	419

Other	185	353
Total	$ 3,015	$ 2,659
Other noncurrent liabilities		
Liability pertaining to uncertain tax position	$ 590	$ 509
Deferred rental liabilities	1,725	79
Other	14	
Total	$ 2,329	$ 588

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12. Fair value of financial instruments

The carrying amounts of financial instruments such as cash equivalents, restricted cash, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company may invest its excess cash into financial instruments that are readily convertible into cash, such as marketable securities, money market funds and certificates of deposit with original maturities of three months or less at the date of purchase. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company has established guidelines to maintain safety and liquidity for our financial instruments, and the cost of securities sold is based on the specific identification method.

ASC Topic 820, Fair Value Measurements and Disclosures has redefined fair value and required the Company to establish a framework for measuring fair value and expand disclosures about fair value measurements. The framework requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company subject to *ASC Topic 820, Fair Value Measurements and Disclosures* and the valuation approach applied to each class of financial instruments, as of December 31, 2012 and 2011, respectively, (in thousands):

	December 31, 2012			
	Quotes Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market fund	$ 20,005	$	$	$ 20,005
Certificate of deposit		25,006		25,006
Preferred securities			1,000	1,000

	December 31, 2011			
	Quotes Prices in Active Markets for Identical Assets	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total

	(Level 1)		
Money market funds	$ 19,225	$	$ 19,225
Certificates of deposit		5,000	5,000

At December 31, 2012, 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

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prices for similar assets or liabilities in active markets and inputs other than quoted prices that are observable for the asset or liability. Level 3 assets and liabilities are valued by recent acquisition price and are based on significant unobservable inputs that are supported by little or no market activity. ASC 820-10-52(bbb) states that sometimes fair value is measured on the basis of prices in prior transactions or third party pricing, which the Company used in valuing its preferred securities in a privately-held company.

	31-Dec-12		31-Dec-11	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Financial liabilities:				
Long-term debt	$ 701	$ 677	$ 1,583	$ 1,501

13. Selected quarterly financial data (unaudited)

	2012 Quarters (in thousands, except per share data)			
	First	Second	Third	Fourth
Total revenue	$ 2,159	$ 3,612	$ 5,256	$ 9,442
Gross profit	$ 472	$ 1,447	$ 2,229	$ 4,681
Loss from operations	$ (5,482)	$ (5,581)	$ (6,233)	$ (4,595)
Net loss	$ (5,558)	$ (5,600)	$ (6,252)	$ (4,693)
Per share data:				
Net loss per common share basic and diluted	$ (0.28)	$ (0.26)	$ (0.20)	$ (0.15)

	2011 Quarters (in thousands, except per share data)			
	First	Second	Third	Fourth
Total revenue	$ 758	$ 901	$ 1,316	$ 2,034
Gross profit (loss)	$ (743)	$ (393)	$ (469)	$ 408
Loss from operations	$ (6,649)	$ (5,715)	$ (6,105)	$ (5,394)
Net loss	$ (6,642)	$ (5,580)	$ (6,313)	$ (5,435)
Per share data:				
Net loss per common share basic and diluted	$ (0.56)	$ (0.39)	$ (0.31)	$ (0.27)

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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 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, 2012, our disclosure controls and procedures were effective.

Previously Reported Material Weakness

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2011 as required by paragraph (b) of Rule 13a-15 or Rule 15d-15 of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of that date, our disclosure controls were not effective at a reasonable assurance level because of the identification of a material weakness in our internal control over financial reporting as of December 31, 2011, which we view as an integral part of our disclosure controls and procedures.

During the preparation of our 2011 financial statements, there were current period and prior period errors identified by our external auditors and our management, as well as other internal control deficiencies. These errors and deficiencies resulted in the need to record adjustments that were immaterial individually and in the aggregate; however, due to the quantity of deficiencies identified, management determined that there was a reasonable possibility that a material misstatement to our annual or interim financial statements might not have been prevented or detected in a timely manner. Specifically, the level of monitoring of our financial closing and reporting process was insufficient to reduce the likelihood of detecting material adjustments to our books and records.

As a result, management identified a material weakness in our internal control over financial reporting related to the supervision and review of our financial closing and reporting process as of December 31, 2011. This material weakness was originally reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011.

Remediation Efforts to Address our Previously Reported Material Weakness

During the quarter ended March 31, 2012, our Audit Committee initiated a review of our internal control culture, our finance and accounting organizational structure, and the findings of our external auditor. As a result

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of this initial review, we identified four primary areas requiring corrective action in order to remediate our material weakness, which consisted of:

- evaluating our Finance Department s management and staff qualifications, which resulted in us making certain personnel changes including the replacement of our Chief Financial Officer, Controller and certain accounting staff;
- redesigning and implementing structured and formalized internal control procedures;
- implementing new control procedures over the utilization of external resources; and
- developing and initiating a plan for the deployment of additional software systems to assist in automating and controlling certain financial processes.

During the second, third and fourth quarters of 2012, we undertook further efforts to address the areas we identified as requiring corrective action in order to remediate our material weakness, which required a substantial commitment of time and the deployment of additional resources. This remediation process included the creation of a significant number of new internal controls, the redesign of certain previously existing internal controls and the retraining of staff on certain previously existing internal controls.

Our management believes that these efforts have improved our internal control over financial reporting and that, as of December 31, 2012, we have remediated our previously reported material weakness. However, any system of controls, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the system of control are or will be met, and no evaluation of controls can provide absolute assurance that all control issues within a company have been detected or will be detected under all potential future conditions.

Changes in Internal Control Over Financial Reporting

With the exception of the remediation efforts described above, there has been no change in our internal control over financial reporting that occurred in the annual period covered by this report 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.

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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, 2012 based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

GenMark Diagnostics, Inc.

Carlsbad, California

We have audited the internal control over financial reporting of GenMark Diagnostics, Inc. and subsidiaries (the Company) (formerly Osmetech plc and subsidiaries) as of December 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We 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 by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel 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 the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2012, of the Company and our report dated March 14, 2013, expressed an unqualified opinion on those consolidated financial statements.

/s/ DELOITTE & TOUCHE LLP

San Diego, California

March 14, 2013

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ITEM 9B. OTHER INFORMATION

None.

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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 Information Regarding the Board of Directors and Corporate Governance, Executives and Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement to be filed in connection with our 2013 Annual Meeting of Stockholders, or the Proxy Statement.

Code of Ethics

We have adopted a code of ethics for our directors, officers and employees, which is available on our website at www.genmarkdx.com in the Investor Information section under Corporate Governance. If we make any substantive amendments to the code of ethics or grant any waiver from a provision of the code of 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 Compensation Committee Report 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 Related-Person Transactions, Related-Person Transactions Policy and Procedures and Information Regarding the Board of Directors and Corporate Governance 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 Pre-Approval Policies and Procedures contained in the Proxy Statement.

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Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULE

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

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2012 and 2011

Consolidated Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2012

Consolidated Statements of Stockholders Equity for each of the three years in the period ended December 31, 2012

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2012

Notes to Consolidated Financial Statements

2. 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.

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SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 14, 2013.

GENMARK DIAGNOSTICS, INC.

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

March 14, 2013

By: /s/ RICHARD B. SLANSKY
Name: Richard B. Slansky
Title: Chief Financial Officer
(principal financial officer and principal accounting officer)

March 14, 2013

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ HANY MASSARANY **Hany Massarany**	President, Chief Executive Officer and Director (principal executive officer)	March 14, 2013
/s/ RICHARD B. SLANSKY		March 14, 2013

Richard B. Slansky	Chief Financial Officer (principal financial officer and principal accounting officer)	
/s/ Christopher Gleeson **Christopher Gleeson**	Chairman of the Board	March 14, 2013
/s/ Daryl J. Faulkner **Daryl J. Faulkner**	Director	March 14, 2013

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Signature	Title	Date
/s/ James Fox **James Fox**	Director	March 14, 2013
/s/ Kevin C O Boyle **Kevin C O Boyle**	Director	March 14, 2013
/s/ Stephen Worland **Stephen Worland**	Director	March 14, 2013

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INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
3.2	Bylaws (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
4.1	Form of Warrant (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 13, 2010).
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.ü
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.ü
10.6	Amended and Restated License Agreement by and between President and Fellows of Harvard College and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated July 14, 1997 (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	Amendment No. 1 to the Amended and Restated License Agreement dated June 7, 2005 by and between Clinical Micro Sensors, Inc. and President and Fellows of Harvard College.ü
10.8	Amendment No. 2 to the Amended and Restated License Agreement dated January 14, 2006 by and between Clinical Micro Sensors, Inc. and President and Fellows of Harvard College.ü
10.9	Exclusive License Agreement by and between Marshfield Clinic and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated October 15, 2007 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 25, 2010).
10.10	Non-Exclusive Patent License Agreement by and between the University of Washington and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 28, 2007 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 21, 2010).
10.11	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).

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Exhibit Number	Description
10.12	License Agreement by and between the Regents of the University of Michigan, HSC Research and Development Limited Partnership and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated March 15, 2006 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 21, 2010).
10.13	License Agreement by and between HSC Research and Development Limited Partnership and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated March 15, 2006 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 25, 2010).
10.14	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).
10.15	Heads of Agreement by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Advanced Liquid Logic, Inc. dated effective as of March 30, 2012 (incorporated by reference herein to our Form 10-Q as filed with the SEC on May 10, 2012).
10.16	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 as filed with the SEC on November 8, 2012).
10.17	License Agreement dated March 22, 2010 by and between Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics and Siemens Healthcare Diagnostics Inc.ü
10.18	2010 Equity Incentive Plan (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).*
10.19	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).*
10.20	Form of Restricted Stock Agreement (incorporated by reference herein to our Form 10-Q as filed with the SEC on November 9, 2010).*
10.21	Form of Restricted Stock Unit Agreement and Grant Notice (incorporated by reference herein to our Form 8-K as filed with the SEC on March 12, 2013).*
10.22	Form of Amendment of Restricted Stock, Restricted Stock Unit and/or Stock Option Agreement(s).*ü
10.23	The GenMark Diagnostics, Inc. 2013 Bonus Plan (incorporated by reference herein to our Form 8-K as filed with the SEC on March 12, 2013).*
10.24	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).*
10.25	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).*
10.26	Executive Employment Agreement, dated as of April 5, 2011, by and between GenMark Diagnostics, Inc. and Hany Massarany (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 13, 2011).*

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Number	Description
10.27	Executive Employment Agreement, dated March 23, 2012, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Richard B. Slansky (incorporated by reference herein our Form 8-K filed with the Securities and Exchange Commission on April 2, 2012).*
10.28	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).*
10.29	Executive Employment Agreement dated April 13, 2010 by and between Osmetech Molecular Diagnostics and Jennifer Williams.ü*
10.30	Executive Employment Agreement dated February 6, 2012 by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Jorge Garces (incorporated by reference herein from our Form 10-K as filed with the SEC on March 21, 2012).*
10.31	Separation Agreement and General Release by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Paul Ross, dated April 19, 2012 (incorporated by reference herein from our Form 10-Q as filed with the SEC on May 10, 2012).*
10.32	Separation Agreement and General Release, dated August 21, 2012, by and between Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. and Matthew Cohen (incorporated by reference herein from our Form 10-Q as filed with the SEC on November 8, 2012).*
10.33	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 November 8, 2012).
10.34	Reagent Rental Agreement, dated September 27, 2012,, by and between Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. and Natural Molecular Testing Corporation (incorporated by reference herein from our Form 10-Q/A as filed with the SEC on November 8, 2012).
21.1	List of Subsidiaries (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 13, 2010).
23.1	Consent of Deloitte & Touche LLP (US). ü
24.1	Power of Attorney (included on the signature page hereto). ü
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. ü
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. ü
32.1	Certification of the principal executive officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350. ü
32.2	Certification of the principal financial officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. section 1350. ü
101	XBRL Instance Document±
101	XBRL Taxonomy Extension Schema Document±
101	XBRL Taxonomy Calculation Document±
101	XBRL Taxonomy Definition Linkbase Document±

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Exhibit

Number	Description
101	XBRL Taxonomy Label Linkbase Document±
101	XBRL Taxonomy Presentation Linkbase Document±

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

ü Included in this filing.
GenMark Diagnostics, Inc. has requested confidential treatment with respect to certain portions of this exhibit.

± Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.