GenMark Diagnostics, Inc.
Form 10-K
March 14, 2011
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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, 2010

¨ **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 ¨ No ¨

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x	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 30, 2010, the last business day of the registrant s most recent completed quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $30,282,224 based on the closing sale price for the registrant s common stock on the NASDAQ Global Market on that date of $4.09 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, 2011 was 11,728,233. 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 for the 2011 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the year ended December 31, 2010, are incorporated by reference in Part III of this Form 10-K

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Forward-Looking Statements

This Annual Report on Form 10-K, particularly in Item 1. Business and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated 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. 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 and plans and objectives of management for future operations. When used in this Annual Report, the words believe, may, could, will, estimate, continue, anticipate, intend, expect, and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to certain risks and uncertainties that could cause our actual results to differ materially from those reflected in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report, and in particular, the risks discussed under the heading Risk Factors and those discussed in other documents we file with the Securities and Exchange Commission. 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 report and in the documents incorporated in this report 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.

PART I.

Item 1. BUSINESS

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware in February 2010, and had no operations prior to its initial public offering which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of (i) the issuance of common stock of GenMark to the former shareholders of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a subsidiary controlled by GenMark, and the former shareholders of Osmetech began to hold shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization.

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 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 30 minutes of

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receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports up to 24 independent test cartridges, of which each can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are hospitals and reference laboratories.

We have developed four diagnostic tests for use with our XT-8 system and expect to expand this test menu by introducing two to four new tests annually. Our Cystic Fibrosis Genotyping Test, which detects pre-conception risks of cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual s ability to metabolize the oral anticoagulant warfarin, and our Thrombophilia Risk Test, which detects an individual s increased risk of blood clots, have received FDA clearance. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed a Respiratory Viral Panel Test, which detects the presence of major respiratory viruses and is labeled for investigational use only, or IUO. We intend to seek FDA clearance for our Respiratory Viral Panel Test in the second quarter of 2011. We also have a pipeline of several additional potential products in different stages of development or design, including diagnostic tests for an individual s sensitivity to Plavix, a commonly prescribed anti-coagulant, and for mutations in a gene known as K-ras, which is predictive of an individual s response rates to certain prescribed anti-cancer therapies.

We are also developing our next-generation platform, the NexGen system. We are designing the NexGen system (formerly referred to as the AD-8 system) to integrate DNA amplification with our eSensor detection technology to enable technicians to place a minimally prepared patient sample 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.

Our XT-8 system and planned menu of tests are intended to improve patient care and physician practices by providing high value, clinically useful information that aids in the diagnosis of disease and the selection of treatments tailored to an individual s genetic profile. We believe that these improvements in patient care are economically attractive to our customers who are generally reimbursed for these tests by third-party payors and managed care providers through established reimbursement codes. Given historically positive reimbursement levels and because the XT-8 system is designed to be flexible and easy-to-use, we believe that our customers will choose to perform a broad range of tests on our platform, in some cases providing our customers with sources of diagnostic test revenue previously unavailable to them. By focusing our product development and commercialization efforts on high value, clinically useful opportunities in genetic and infectious diseases, cancer and personalized medicine, we believe we will drive widespread clinical adoption of 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:

Expand our Menu of Clinical Diagnostic Products. We intend to develop a broad menu of molecular diagnostic tests that we believe satisfy important medical needs and will be attractively reimbursed by third-party payors. We are pursuing and intend to continue to pursue FDA clearance or approval for our tests. We intend to explore tests that are either already in high demand or projected to experience rapid growth. We plan to gain access to these tests by in-licensing, where required, the appropriate biomarkers that have shown correlations to diseases or therapeutic response.

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

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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.

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 will 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 will retain all the customer benefits of our XT-8 system while also integrating automated nucleic acid extraction and amplification. These features will eliminate the need for time consuming and complex sample preparation steps and allow technicians to place a raw or minimally prepared patient sample into our test cartridge. We have already demonstrated feasibility of direct sample to answer on a NexGen system prototype using diluted blood. We believe this advancement will make our technology 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 such workflow enhancements may expand our target user base from some 1,000 customers to over 5,000 potential customers in the United States.

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 are developing a distribution strategy for European and other international markets. 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 out-licensing or the establishment of partnerships.

Our Products

Out 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 module into which the self-contained, disposable test cartridges are inserted. The 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. Specifically, 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 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 and Thrombophilia Risk Test, and our Respiratory Viral Panel Test, which is labeled for IUO, we have a pipeline of several additional products in development or design in the fields of pharmacogenetics, genetic diseases, infectious diseases and cancer. We are currently developing a Plavix Sensitivity Test and a K-ras Mutation Test, and we have a pipeline of potential products in various stages of development or design. Laboratories using our system will be able to run the additional tests we offer without any additional capital investment or operator training.

FDA-Cleared Products. We have received FDA clearance for our Cystic Fibrosis Genotyping Test, Warfarin Sensitivity Test and Thrombophilia Risk Test, while our Respiratory Viral Panel Test is labeled for IUO. We intend to submit our Respiratory Viral Panel Test to the FDA for clearance in 2011. We intend to utilize IUO-labeled products in clinical studies within the broader process of seeking FDA clearance for our diagnostic tests.

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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 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 tests while 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 30 minutes of receipt of the amplified DNA sample, resulting in a total turnaround time of generally 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.

Our XT-8 system consists of a compact bench-top workstation with an integrated touch screen computer and an analyzer module into which the self-contained, disposable test cartridges are inserted. These features make the XT-8 system user-friendly, intuitive and virtually maintenance-free. With a footprint of approximately 16-by-16 inches in its standard configuration, the XT-8 system takes up less bench top space than most of our competitors systems, and its standalone design allows it to be installed and used without any required laboratory modifications.

Prior to performing a test, a laboratory technician takes isolated DNA from the patient sample and performs a DNA 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 module. 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 takes under four hours to complete, and the test results can be viewed on the built-in touch screen monitor 30 minutes after the insertion of test cartridges into the XT-8. Test results can also be printed out or reported through the laboratory s computer information system.

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The key features of our XT-8 system include:

Key Features	Characteristics
Ease of Use	Intuitive touch-screen interface and clear reports
Multiplex Capability	Detects up to 72 distinct biomarkers in a single sample
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
Fast Turnaround	30 minutes to result from amplified DNA sample with minimal technician time needed
Random Access	Each of up to 24 test cartridge slots can be accessed independently
Minimal Maintenance	No routine maintenance or calibration required
Small Footprint	Approximately 16 inches in width and depth in its standard configuration

Our Test Menu

We have developed four diagnostic tests for use with our XT-8 system, three of which have received clearance from the FDA and one of which is currently labeled for IUO. During the fiscal year ended December 31, 2010, sales of our Cystic Fibrosis Genotyping Test represented approximately 43% of our revenues, and sales of our Warfarin Sensitivity Test represented approximately 13% of our revenues.

Cystic Fibrosis Genotyping. 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 compared to DNA sequencing 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 2009 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. 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 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 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 delivers results within 30 minutes of receipt of the amplified DNA sample. Our Warfarin Sensitivity Test received FDA clearance in July 2008.

According to the Medco-Mayo Warfarin Effectiveness Study, there were approximately two million new patient prescriptions of warfarin in the United States in 2009. According to Biotechnology Healthcare 2008, a health-care focused journal, there were approximately 20 million patients on warfarin therapy in 2008. The FDA recently approved a labeling change that provides dose recommendations based on genetic test results.

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Thrombophilia Risk. 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 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. Our Thrombophilia Risk Test demonstrated 100% accuracy in clinical studies compared to DNA sequencing 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). Our Respiratory Viral Panel Test, currently labeled for IUO, covers approximately 20 viruses, including influenza A (H1N1 and seasonal), influenza B, respiratory syncytial virus, or RSV, and numerous other upper respiratory viruses. We have initiated clinical studies on our RVP panel and currently plan to submit it for FDA clearance in 2011.

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; more than 200,000 people are hospitalized from flu-related complications; and about 36,000 people die from flu-related causes. 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. The challenge to the physician assessing a patient with a respiratory illness is determining what the underlying cause is so that an effective treatment plan can be determined.

Our Tests in Development and Design

We have a pipeline of potential products in various stages of development or design. We consider our diagnostic tests to be in the design phase once they have advanced beyond the conceptual stage. We perform market research, clinical publication reviews, customer interviews, technical feasibility and freedom to operate assessments to determine if a potential diagnostics test is a viable product candidate. We believe that all of our tests in the design stage have viable market potential and are technically feasible to develop using our eSensor technology. While we do not currently license biomarkers for all products in the design phase, we believe we will be able to obtain such licenses, if needed, on commercially reasonable terms.

We intend to introduce two to four new tests annually and currently expect that our Plavix Sensitivity Test, our Hepatitis C Viral Genotyping test and our K-ras test will be our first tests in development and design to be introduced. We select these tests based upon what we believe are clinically relevant products which address unmet market needs. Laboratories using our XT-8 system will be able to run the additional tests we offer without any additional capital investment or operator training. We are currently developing or designing the following diagnostic tests:

Plavix Sensitivity. Plavix is the most commonly prescribed anti-platelet drug with more than 25 million patients taking the drug in the United States each year. According to the Cheuvreux Sector Report, a market research report, over 1.6 million new patients were prescribed Plavix in 2009. In order for Plavix to be effective, it must be metabolized by the body using an enzyme referred to as 2C19. Patients with impaired 2C19 functionality will see reduced metabolism and therefore, reduced benefits from taking Plavix. We are currently in late stage development for a 2C19 multiplex genetic test that detects a panel of genetic markers associated with poor metabolism of Plavix. The FDA has recently revised the label for Plavix with a black box that warns of the reduced effectiveness of Plavix in patients who are poor metabolizers and informs physicians of the existence of genetic tests to identify these at-risk patients.

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Plavix s patents are expected to expire in late 2011, and we believe this expiration will lead to significant generic competition which will drive down the cost for Plavix and increase overall demand for the drug. According to the Plavix label, 2% to 14% of patients do not respond to Plavix. As a result, we believe there will be increased demand for the Plavix Sensitivity Test as third-party payors will have an added incentive to reimburse for a test that can reduce or avoid the use of expensive next-generation anti-platelet therapies.

Infectious Disease Test Panels. The infectious disease diagnostics market is estimated to reach over $6 billion in the United States by 2012, with substantial growth expected in the molecular diagnostic segment. 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 XT-8 system placements in the acute care setting. The test panels we are designing fit into two categories: Genotyping tests for viruses such as hepatitis C virus (HCV) and human papillomavirus (HPV) or detection tests for panels of viruses, bacteria or fungi such as central nervous system infections or 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 RVP product, we intend 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 or development stage. These include: Lower Respiratory Tract Infections (LRTI); Central Nervous System Infections (CNS); and Hepatitis C Virus Genotyping (HCVg).

K-ras Mutation. Anti-EGFR therapy is a type of cancer treatment that interferes with the growth of cancer cells, slowing their growth and subsequent spread in the body. Anti-EGFR therapy is currently approved by the FDA to treat colorectal cancer as well as head and neck cancer. Scientific studies have demonstrated that patients whose tumors have genetic variations in the K-ras gene will not respond to anti-EGFR therapy. Currently approved anti-EGFR therapies are marketed under the brand names Erbitux and Vectibix. These therapies are approved for use in colorectal cancer and more recently head and neck cancer in the case of Erbitux.

According to the American Cancer Society, there are over one million new cases of colorectal cancer globally each year with approximately 150,000 cases in the United States alone. We are currently developing a multiplex K-ras test that detects a panel of common genetic markers in the K-ras gene. The FDA requires K-ras testing on the labels of the two approved anti-EGFR antibody therapeutics, Vectibix and Erbitux, for use in colorectal cancer.

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 XT-8 system placements in these laboratories. Examples of tests panels that are under design include 2D6 for Tamoxifen Metabolism, which can affect the effectiveness of a drug used for the treatment and prevention of breast cancer, and EGFR Pathway, which detects mutations in genes other than K-ras involved in EGFR signaling.

Our NexGen System

We are developing our next-generation testing system to integrate automated nucleic acid extraction and amplification. We are designing the NexGen system (formerly referred to as our AD-8 system) to allow a technician to place a patient sample into our test cartridge and then insert the cartridge in the NexGen system with no further user interventions. The NexGen system is designed to achieve full sample to answer capability. The NexGen system will provide the same customer benefits of the XT-8 system and further enhance workflow by reducing the level of sample processing required and incorporating amplification. We believe this advancement will make our eSensor technology attractive to the broad range of institutions that currently lack the

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technical or economic resources to perform molecular diagnostic testing. We believe the NexGen system may expand our target user base from 1,000 to over 5,000 potential laboratories and hospitals in the United States.

The NexGen system is currently in development with substantial technical feasibility completed using diluted blood in our Warfarin Sensitivity Test. The NexGen system leverages the base technology and system hardware from our XT-8 system to reduce risk and accelerate the development of the sample preparation and amplification features. We believe our approach to a sample to answer system will achieve benefits over other competitive multiplex systems, which require extensive sample processing procedures in addition to other complex sample manipulations throughout their test process.

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 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 the XT-8 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 test cartridges is a 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 Test Cartridges. Our 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 assay identifier, cartridge lot number and expiration date.

Our XT-8 System. Our XT-8 system is a multiplex workstation that has a modular design consisting of an integrated touch screen workstation and up to three analyzer modules each capable of analyzing eight individual test cartridges. The test cartridge slots operate independently of each other allowing up to 24 independent test

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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 module, 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:

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 by our eSensor technology. This robust functionality will, we believe, 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 1 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 clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test.

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.

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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 fluidic handling and 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 XT-8 system 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 XT-8 system. This ease of assay development and our versatile platform allows 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.

Research and Development

As of December 31, 2010, we had 20 employees focused on research and development. In 2010, we moved our research and development activities to our new 31,000 square foot headquarters in Carlsbad, California. Our research and development expenditures were approximately $6.5 million, $5.6 million and $13.4 million for the years ended December 31, 2010, 2009 and 2008, respectively. The overall reduction from 2008 in research and development expenses was due to the completion of our XT-8 system in 2009. The increase from 2009 to 2010 was due to higher payroll costs, relocation and recruitment costs and higher facility allocations.

In addition to expanding the diagnostic test menu for our XT-8 system and developing our NexGen system, 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 are also exploring 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 with our XT-8 system.

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Manufacturing

We manufacture our proprietary test cartridges and ancillary reagents at our approximately 8,400 square foot facility in Pasadena, California. We began the transfer of our manufacturing operations to our new 31,000 square foot headquarters in Carlsbad, California and expect to complete the move in March 2011. Our reagent formulation, test cartridge manufacturing and packaging of final components and cartridges are performed by us in accordance with applicable guidelines for medical device manufacturing. We outsource manufacturing of our XT-8 system, as well as the oligonucleotide raw materials and much of the disposable component molding and sub-component assembly for our test cartridges. In particular, our XT-8 system is manufactured by a single source supplier that specializes in contract design and manufacturing of electronic and electromechanical devices for medical use. We believe we can secure other suppliers on commercially reasonable terms for the products and parts we outsource.

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. We also have controlled methods for the consistent manufacturing of our proprietary test cartridges and reagents at our facilities. All key outsourcing partners are generally ISO-certified to help assure a continual supply of high quality components.

We plan to continue to manufacture components that we determine are highly proprietary or highly custom to produce, while outsourcing more commodity-like components. We are likely to establish additional outsourcing partnerships as we manufacture additional products. We believe our existing facilities as well as our new facility in Carlsbad, California will be adequate to meet our current and future manufacturing needs.

Sales and Marketing

Our sales and marketing strategy is to expand the installed base and utilization of the XT-8 platform and consumables. Our products are sold in the United States through a geographically dispersed seven person direct sales and technical specialist service organization. They are supported by a centralized team of Product Managers, Marketing, Customer and Technical Support personnel.

Our sales representatives typically have extensive 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 next generation detection platform, we continue to make investments in these customer facing organizations.

We believe the XT-8 platform competes largely on the basis of improved performance and reliability, ease of use and streamlined laboratory workflow, a high value IVD menu with multiplexing capabilities, and a superior return on investment. These and other advantages conferred by our chemistry 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 cartridges over the term of the agreement, and a portion of the charge for each cartridge is a rental fee for the equipment. Our reagent rental agreements do not typically provide for any cancellation rights by the customer. The reagent rental agreements do allow us to remove, change or upgrade the XT-8 system at any time.

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

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cartridge commitment. Through December 31, 2010, we sold ten XT-8 systems to customers which include the sale of thirteen analyzers to customers with each analyzer capable of analyzing eight test cartridges at one time.

In the second half of 2011, we anticipate commencing planning for commercialization of our molecular diagnostic products in Europe and other international markets. We anticipate our sales and marketing strategy will involve a select network of partners and distributors. A distribution strategy is being developed for each relevant international market. It is expected that we will augment this effort with a team of our specialists who will enable our partners sales forces and provide technical support. We also intend to explore opportunities to leverage our intellectual property position in molecular diagnostics through out-licensing or the establishment of partnerships.

Customers

In 2010 and 2009, 28% and 38% of our revenues, respectively, were attributed to our three largest customers during the year. In 2010, one customer accounted for approximately 12% of our total revenues. We do not believe the loss of one of these customers would have a material adverse effect on our business, financial condition and results of operation.

During 2010, we redefined the XT-8 system to be a system consisting of one control system and up to three analyzers, with each analyzer capable of analyzing eight test cartridges at the one time. Placements are defined in terms of the number of analyzers sold to a customer, reflecting a direct correlation between the reagent test revenue opportunity and the number of test cartridges that can analyzed at any one time. As of December 31, 2010, there were 82 analyzers at 67 unique customer sites, or approximately 1.2 analyzers per customer. This compares with 38 analyzers at 32 unique customer sites, or approximately 1.2 analyzers per customer as of December 31, 2009.

The increase in analyzers and related revenue is due to an increase in the number of new customers buying our products and growth in additional tests from existing customers. We expect our clinical molecular diagnostic revenues to continue to increase in 2011.

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, Gen-Probe, Inc., Siemens, Hologic, Inc., Innogenetics, Inc, Luminex Corporation, Nanosphere, Inc., Qiagen NV, Roche Diagnostics and Abbott Diagnostics. Our diagnostic tests also face competition with the laboratory developed tests developed by national and regional reference laboratories and hospitals. We believe that the 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 patent, copyright, trademark and trade-secret laws, as well as confidentiality provisions in our contracts. We have implemented a patent strategy designed to protect our technology and facilitate commercialization of our current

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and future products. As of December 31, 2010, our patent portfolio included 100 U.S. patents, 44 foreign patents (predominantly in Europe and Japan) and 49 pending domestic and foreign patent applications, all of which are either owned by us or are exclusively licensed to us. Our intellectual property portfolio for our core electrochemical technology was built through the combination of our acquisition of the Clinical Micro Sensors business from Motorola, licensing patents from third parties and the issuance of new patents to us to protect our ongoing development activities. Many of our issued and pending patents were exclusively licensed from the California Institute of Technology and Harvard University and generally cover our core technology relating to our XT-8 system.

We believe that our patent portfolio and licenses provide us with a robusst intellectual property position for our electrochemical detection techniques, chemical insulators and attachment points on electrode surfaces and other technology that collectively form the staple of our eSensor platform.

In general, patents have a term of 20 years from the application filing date or earlier claimed priority date. Our issued and exclusively licensed patents will expire between 2013 and 2021 or later, with several of our pending applications having the potential to mature into patents that might expire in 2027, 2028 and 2029. 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 on 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, soliciting employees and soliciting customers.

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

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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 and Thrombophilia Risk 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 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, 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.

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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;
- 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. If the FDA s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA 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 PMA 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. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is 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.

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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.

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 use of extraordinary disposal practices. Although the costs to comply with these applicable laws and regulations have not been material, we can not predict the impact on our business of new or amended laws or regulations or any changes in the way existing and future laws and regulations are interpreted or enforced, nor can we ensure we will be able to obtain or maintain any required licenses or permits.

Export of Our Products. 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, including, among other things and with some exceptions, 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 the public health or safety.

Clinical Laboratory Improvement Amendments of 1988. The use of our products is also affected by 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.

Other Legislation. On September 27, 2007, the President signed the Food and Drug Administration Amendments Act of 2007, or FDAAA. Among other significant changes and requirements it imposes, the new legislation expands the federal government s clinical trial registry and results databank maintained by the NIH to include all (with limited exceptions) medical device trials. In particular, it requires certain information about device trials, including a description of the trial, participation criteria, location of trial sites, and contact information, to be sent

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to NIH for inclusion in a publicly accessible database. In addition, the results of clinical trials that form the primary basis for efficacy claims or are conducted after a device is approved or cleared must be posted to the results databank. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties.

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 not be sufficient to cover costs and may not be made permanent.

Successful sales of our products in the United States and other countries will 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 eSensor Cystic Fibrosis Genotyping Test and eSensor Thrombophilia Risk Test for the XT-8 system and we believe that each of our tests in development are covered by existing CPT codes and will be eligible for coverage by Medicare and Medicaid and most third-party payors. However, Medicare and Medicaid generally do not reimburse providers who use our Warfarin Sensitivity Test. In 2010, the American Medical Association formed a molecular pathology working group to provide recommendations for modernization of codes for molecular diagnostic and genetic tests. This group is expected to issue recommendations in 2011 that will be considered for implementation in 2012. 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.

In addition, we may develop tests in the future that do not relate to previously established CPT codes and we may need to obtain new CPT codes in order to obtain reimbursement. 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 can not receive sufficient levels of reimbursement when using our products, our ability to sell them will 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

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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, could be forced to expend significant resources on investigation, remediation and monetary penalties.

Patient Protection and Affordable Care Act

Our operations will also be impacted 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 expect to begin paying the tax in 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. We expect compliance with the Health Care Act to impose significant administrative and financial burdens on us.

Employees

As of December 31, 2010, we had 79 employees. Approximately 20 are involved in research and development, 30 in operations, manufacturing and quality assurance, 18 in sales and marketing, and 11 in finance, legal and other 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.

Executive Officers

Our executive officers and their ages as of December 31, 2010, are as follows:

Christopher Gleeson, age 61, has served as Chief Executive Officer, on an interim basis, since August 2010. Mr. Gleeson has also served as Chairman of the Board of GenMark Diagnostics since March 2010 and chairman of the board of Osmetech plc since July 2009. Prior to this time, Mr. Gleeson was President and Chief Executive Officer of Ventana Medical Systems, Inc., a leading supplier of automated diagnostic systems to the anatomical pathology market from 1999 to February 2008. Following the acquisition of Ventana by Roche Diagnostics in February 2008, Mr. Gleeson became a member of the board of directors of Roche Diagnostics. Prior to joining Ventana, Mr. Gleeson was Senior Vice-President of Bayer Diagnostics, the diagnostics division of Bayer Healthcare Pharmaceuticals and general manager of the U.S. commercial operations for Chiron Diagnostics, the diagnostics division of Chiron Corporation. Prior to that time, he was the founder, owner, and managing director of Australian Diagnostics Corporation. Mr. Gleeson attended the Pharmacy and Business Schools at Monash University in Australia.

Jon Faiz Kayyem, Ph.D., age 47, has served in the capacity of Chief Scientific Officer of GenMark Diagnostics, Inc. since August 2010 and as Director since March 2010. Dr. Kayyem previously served as President and Chief Executive Officer of GenMark Diagnostics, Inc. between March 2010 and August 2010. Prior to his role at

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GenMark Diagnostics, Inc. Dr. Kayyem served as President and Chief Executive Officer of Osmetech plc since August 2009 and chairman of the board of directors of Osmetech plc from January 2009 to August 2009. In 2004, Dr. Kayyem co-founded Efficacy Capital Limited and served as managing partner until September 2009. Dr. Kayyem founded Clinical Micro Sensors Inc. in 1995 where commercialized technological innovations he developed at Caltech. Dr. Kayyem led the development and growth of Clinical Micro Sensors through its acquisition by Motorola, Inc. Dr. Kayyem attended Yale University and received his combined Master and Bachelor of Sciences in Molecular Biophysics and Biochemistry in 1985. He received his Ph.D. in Molecular Biology in 1991 at The California Institute of Technology.

Jeffrey Hawkins, age 33, has served as Senior Vice President, Marketing and Business Development of GenMark Diagnostics, Inc. since November 2010. Prior to his appointment in 2010, Mr. Hawkins served as Vice President of Business Development for GenMark Diagnostics since May 2010 and in the same capacity for Osmetech Technology, Inc, a wholly-owned subsidiary of Osmetech plc, since December 2009. Prior to Osmetech, Mr. Hawkins served as Executive Director, Laboratory Marketing of Hologic Inc. from July 2008 to December 2009 and as Executive Director of Marketing of Third Wave Technologies Inc. (acquired by Hologic) from November 2006 to July 2008. Mr. Hawkins has previously served in various roles of increasing responsibility in marketing, product development and operations with Sysmex America and Abbott Laboratories. Mr. Hawkins received a B.A. in Chemistry with honors from Concordia University and an M.B.A from Keller Graduate School of Management.

Pankaj Singhal, age 39, was appointed Senior Vice President, Product Development of GenMark Diagnostics, Inc. in July 2010. Previously, Dr. Singhal served as Senior Vice President, Product Development and Manufacturing of Osmetech Technology, Inc, a wholly-owned subsidiary of Osmetech plc, since March 2010. Dr. Singhal served as Chief Operating Officer of Osmetech Technology, Inc. from May 2008 through March 2010. Prior to that time, he served as Vice President of Operations of Osmetech Technology from January 2007 to April 2008 and Director of Manufacturing Operations from July 2005 to December 2006. Dr. Singhal joined Clinical Micro Sensors in 2000 and remained with Osmetech plc following Osmetech s acquisition of Clinical Micro Sensors from Motorola in 2005. Dr. Singhal received a B.S. in Chemical Engineering, and a Ph.D. in Chemistry from University of California, Riverside. He also conducted postgraduate fellowship work at the University of California, Berkeley in the areas of DNA chips, electrochemical detection and signal processing.

Jennifer Williams, age 38, was appointed Senior Vice President of Global Operations in November 2010, and is responsible for Manufacturing Operations, Human Resources and Asia Pacific Commercial Operations. Prior to joining GenMark, Jennifer held the position of Senior Human Resource Executive with Cerberus Operations and Advisory Company, a private equity firm, from February 2008 to May 2010, responsible for human resources oversight and transformation of global companies in the portfolio. From January 2005 to January 2008, Jennifer was Vice President Human Resources at HD Supply, a wholesale distribution company serving the infrastructure, construction, and maintenance markets, initially as part of The Home Depot organization and subsequently spun off in 2007. Previous to that, Ms. Williams led Talent Management for The Home Depot including organization design, succession planning, leadership programs, and executive development. Jennifer began her career at Honeywell (formerly AlliedSignal) and held positions of increasing responsibility in Quality, Operations, Program Management, and Organization Effectiveness. Ms. Williams received her MBA from Case Western Reserve in Organizational Behavior and an undergraduate degree in Industrial and Operations Engineering from the University of Michigan. Ms. Williams holds a certification in Organization Design and is a Six Sigma greenbelt.

Corporate and Available Information

Our principal corporate offices are located at 5964 La Place Court, Suite 100, Carlsbad, California and our telephone number is (760) 448-4300. We were incorporated in Delaware in February 2010.

Our Internet address is www.GenMarkdx.com. There we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports,

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as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. We also make available on our Internet site public financial information for which a report is not required to be filed with or furnished to the SEC. Our SEC reports and other financial information can be accessed through the investor relations section of our Internet site. The information found on our Internet site 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.

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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. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business operations. 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.

Risks Related to Our Business

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 commenced offering our XT-8 system and our Warfarin Sensitivity Test in July 2008. We commenced offering our Cystic Fibrosis Genotyping Test in July 2009 and our Thrombophilia Risk Test in April 2010. Our Respiratory Viral Panel Test is currently labeled for IUO. Our net losses from continuing operations were approximately $18.4 million for the twelve months ended December 31, 2010, $20.0 million in 2009 and $28.4 million in 2008. At December 31, 2010, we had an accumulated deficit of approximately $144.5 million. We will continue to incur significant expenses for the foreseeable future for our sales and marketing, research and development and regulatory activities and maintaining our existing and obtaining additional intellectual property rights. We can not provide you any assurance that we will ever 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 because the market for molecular diagnostic products is relatively new and rapidly evolving, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

We will need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all. If additional capital is not available, we may have to curtail or cease operations.

Until such time, if ever, as we can generate substantial product revenues, we will be required to finance our operations with our existing cash resources. We will need to raise additional funds in the future to support our operations. We can not be certain that additional capital will be available as needed or on acceptable terms, or at all. If we require additional capital at a time when investment in molecular diagnostics companies or in 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 and these 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. If we raise additional funds through collaborations and licensing arrangements, we could be required to relinquish significant rights to our technologies, products or grant licenses on terms that are not favorable to us.

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 will suffer.

Our success depends on the market s confidence that we can provide reliable, high-quality diagnostics systems and tests. 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 impaired if our products fail to perform as expected. Although our diagnostic systems are designed to be user-friendly, the functions they perform are quite complex, and our products may develop or contain undetected defects or errors.

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If we experience a sustained material defect or error, this could result in loss or delay of revenues, increased costs to produce our tests, delayed 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.

We also face an inherent 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 up to an annual aggregate limit of $7.0 million. 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 would have to be paid out of our cash reserves, which would have a detrimental effect on our financial condition. It is difficult to determine whether we have obtained sufficient insurance to cover potential claims. Also, we can not assure you that we can or will maintain our insurance policies on commercially acceptable terms, or at all. A product liability claim could have a material adverse effect on our business, financial condition and results of operations.

We may fail to successfully expand the menu of diagnostic tests for our XT-8 system, or effectively predict the types of tests our existing and target customers want.

We currently market three FDA-cleared diagnostic tests and have developed one other diagnostic test currently labeled for IUO. In addition, we have several diagnostic tests in the development or design stage. Some hospital-based and reference laboratories may not consider adopting our XT-8 system until we offer a broader menu of diagnostic tests. Although we are developing additional tests to respond to the needs of these laboratories, we cannot guarantee that we will be able to license the appropriate technology, or develop and obtain required regulatory clearances or approvals, for enough additional tests quickly enough or in a manner that is cost-effective. 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, 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 successfully develop and commercialize additional diagnostic tests for use with our XT-8 system, our revenues and our ability to achieve profitability will be 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 very competitive, and we expect the intensity of competition to increase. We compete with many companies in the U.S. engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Categories of competitors include:

- Companies developing and marketing multiplex molecular diagnostics systems;
- Large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods; and
- Healthcare companies that manufacture laboratory-based tests and analyzers.

Such competitors classified in the above categories include: Cepheid; Gen-Probe, Inc.; Siemens; Hologic, Inc.; Innogenetics, Inc.; Luminex Corporation; Nanosphere, Inc.; Qiagen NV; Roche Diagnostics; and Abbott Diagnostics. Our diagnostic tests also face competition with the laboratory-developed-tests (LDT s) developed by national and regional reference laboratories and hospitals. Such laboratory-developed tests may not be subject to the same requirements for clinical trials and FDA submission requirements that may apply to our 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

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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, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. The impact of these factors may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue.

We are reliant on the commercial success of our XT-8 system and our diagnostic tests.

We have primarily placed our XT-8 systems with customers at no initial charge through reagent rental agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years, with a component of the reagent cartridge price allocated to recover the instrument cost. While we also offer our XT-8 systems for sale, we had sold only ten of our systems. We expect sales of our diagnostic tests 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 dedicate a significant portion of our resources to the commercialization of our XT-8 system and our existing FDA-cleared diagnostic tests. Although we intend to develop a broad range of additional diagnostic tests for use with the XT-8 system and our NexGen system, we can not assure you when or if we will obtain FDA clearances for the tests we intend to develop in the future, or whether the market will accept such new products. As a result, to the extent that our XT-8 system and our existing FDA-cleared diagnostic tests are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted and our business operating results and financial condition will be harmed.

We may not be successful in developing our NexGen system.

We are developing a sample to answer platform, the NexGen system. 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 a patient sample into our test cartridge and obtain results with no additional steps. The development of the NexGen system is a complex process, and we may not be successful in completing the development of all the currently intended features and benefits of the system, which may limit its marketability. In addition, before commercializing the NexGen system we will be required to obtain regulatory approval for the system as well as each of the diagnostic tests to be used on the system, including those tests that previously received approval for use with our XT-8 system. If we are unable to successfully develop and obtain regulatory approval for our NexGen system and related diagnostic tests, our business plan will be impaired.

Our financial results will depend on the acceptance among reference laboratories and hospitals, third-party payors and the medical community of our molecular diagnostic technology and products.

Our future success depends on the acceptance by our target customers, third-party payors and the medical community that our molecular diagnostic products are a reliable, accurate and cost-effective replacement for other molecular diagnostic testing methods.

Physician 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 replace their current testing platforms and/or send-out tests, with our XT-8 system and related diagnostic tests. We must also continue to increase the consumable volume on our installed systems.

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

- relative convenience and ease of testing 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;

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- our success in training reference and hospital-based laboratories in the proper use of our products;
- the acceptance in the medical community of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

Manufacturing risks and inefficiencies may adversely affect our ability to produce products.

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. 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.

We currently manufacture our proprietary test cartridges at our Pasadena, California manufacturing facility, until our transfer to the Carlsbad facility is complete in the first quarter 2011. We outsource manufacturing of our XT-8 system and much of the disposable component molding and component assembly for our test cartridges. Our XT-8 system is manufactured by Aubrey Group Inc., our single source supplier that specializes in contract design and manufacturing of electronic and electromechanical devices for medical use. The components are custom-made by only a few outside vendors. Reliance on third-party manufacturers entails risks 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; and
- 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.

We may not be able to meet the demand for our products if one or more of these third-party manufacturers are not able to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers in a timely manner and on terms acceptable to us.

The manufacturing operations for our test cartridges in Pasadena, California 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. Other possible disruptions may include power loss and telecommunications failures. 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 plan to move our existing manufacturing operations in Pasadena, California to a new facility located in Carlsbad, California in the first quarter of 2011. Our new manufacturing facility will be subject to the risks discussed above related to our Pasadena manufacturing facilities. In addition, we will need to get the appropriate regulatory clearances for our new facility before commencing manufacturing operations. We may

experience unexpected delays and costs in opening our new manufacturing facilities, which would have an adverse effect on our business and financial condition.

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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 and key scientific and technical personnel. Our senior managers and other key employees can terminate their relationship with us at any time. We have a small number of senior managers, and the loss of services of any of these managers or our scientific or technical personnel could have a material adverse effect on our business, financial condition and results of operations. 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 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.

Our success may depend upon how we and our competitors anticipate and adapt to market conditions.

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition and new product introductions. New technologies, techniques or products could emerge with similar or better performance or may be perceived as providing better value than our systems and related tests and could exert pricing pressures on our products. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers and prospective customers needs on a timely basis. We will need to respond to technological innovation in a rapidly changing industry and may not be able to maintain our technological advantages over emerging technologies in the future. If we fail to keep pace with emerging technologies, our systems and related tests will become uncompetitive and our market share will decline, which would have a material adverse effect on our 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 the level of our expectations. If distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or we are unable to locate distributors in particular geographic areas, our ability to realize long-term international revenue growth would be materially adversely affected.

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 of other countries 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, it is required that the product 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.

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Our Respiratory Viral Panel Test and other menu items that we develop in the future may have sales that fluctuate on a seasonal basis and, as a result, our results of operations for successive quarters may not accurately reflect full-year trends.

Our Respiratory Viral Panel Test and other menu items that we develop in the future that assist in the diagnosis of illnesses may have sales that fluctuate on a seasonal basis. As a result, our results of operations for successive quarters may not accurately reflect full-year trends. For example, we expect volume of testing for our Respiratory Viral Panel Test generally will decline during the spring and summer season and accelerate during the fall and winter season. As a result, comparison of our results of operations for successive quarters may not accurately reflect trends or results for the full year.

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, conduct clinical studies and obtain regulatory clearances for the additional diagnostic tests we develop;
- the expenses we incur for research and development required to maintain and improve our technology, including developing our next-generation molecular diagnostic system;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.
- the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution;
- 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 diagnostic tests. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a significant shortfall in demand for our products could have an immediate and material adverse effect on our business and financial condition.

If we expand sales of our products outside the United States, our business will be susceptible to risks associated with international operations.

If we execute our plan to expand our operations outside the United States, our inexperience in operating in foreign countries increases the risk that our international expansion will not be successful. Conducting international operations would subject us to new risks that, generally, we have not faced in the United States, including:

fluctuations in currency exchange rates;

unexpected changes in foreign regulatory requirements;

longer accounts receivable payment cycles and difficulties in collecting accounts receivable;

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- difficulties in managing and staffing international operations;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards;
- increased financial accounting and reporting burdens and complexities;
- political, social and economic instability abroad, terrorist attacks and security concerns in general; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our business, results of operations and prospects. Additionally, operating internationally also requires significant management attention and financial resources. We can not be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenues or profitability.

We have limited experience in sales and marketing and may be unable to successfully commercialize our XT-8 system and related diagnostic tests.

We have limited marketing, sales and distribution experience and capabilities. In connection with our XT-8 system, we commenced offering our Warfarin Sensitivity Test in July 2008, our Cystic Fibrosis Genotyping Test in July 2009 and our Thrombophilia Risk Test in April 2010. We are currently in varying stages of development of 4 additional tests:

- KRAS-BRAF: Designed for the multiplexed detection and genotyping of 12 mutations in codons 12 and 13 of KRAS and the V600E mutation in BRAF.
- Hepatitus C Virus Genotyping: Designed to detect and subtype the different genotypes for the Hepatitis C Virus (HCV).
- 2C19: For the multiplexed 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); and
- Respiratory Viral Panel: A qualitative nucleic acid multiplex test designed for the simultaneous detection and identification of multiple respiratory virus nucleic acids and mutations)

As of December 31, 2010, we had 82 analyzers actively in use with customers. Our ability to achieve profitability depends on attracting customers for the XT-8 system and building brand loyalty. To successfully perform sales, marketing, distribution and customer support functions ourselves, we will face a number of risks, including:

- Our ability to attract and retain the skilled support team, marketing staff and sales force necessary to commercialize and gain market acceptance for our technology and our products;

The ability of our sales and marketing team to identify and penetrate the potential customer base, including hospitals, national and regional reference laboratories; and

The difficulty of establishing brand recognition and loyalty for our products.

In addition, we may seek to enlist one or more third parties to assist with sales, distribution and customer support globally or in certain regions of the world. If we do seek to enter into these arrangements, we may not be successful in attracting desirable sales and distribution partners, or we may not be able to enter into these arrangements on favorable terms, or at all. If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, our technologies and products may not gain market acceptance, which would materially impact our business operations.

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Providing XT-8 systems to our customers through reagent rental agreements may adversely affect our liquidity.

The majority our XT-8 systems are sold to customers via reagent rental agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years. We also offer our XT-8 systems for sale. In 2010, we sold ten XT-8 systems to customers which included the sale of thirteen analyzers. The amount of additional capital we may need to raise depends on the amount of our revenues from sales of test cartridges sold through these reagent rental agreements. We do not currently sell enough test cartridges to recover all of our fixed manufacturing expenses associated with the production of our systems and test cartridges, and therefore we currently have a high cost of sales relative to revenue, resulting in a gross loss. If we continue not to sell a sufficient number of test cartridges to offset our expenses associated with these reagent rental agreements, our liquidity will 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 can not eliminate the risk of accidental contamination or discharge and any resultant 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. 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 can not 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 our reorganization in 2010, Osmetech became a subsidiary controlled by GenMark and a controlled foreign corporation for U.S. federal income tax purposes. This organizational structure may create inefficiencies, as certain types of income and investments of Osmetech that otherwise would not be currently taxable under general tax rules, may 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 may be subject to additional U.S. and foreign income tax withholding and result in lower profits. It is our intention in the first half of 2011 to streamline our corporate structure and, by doing so, we may lose some, if not most, of our tax loss carry forward benefits and/or certain activities of the restructuring could become taxable transactions. We cannot predict the outcome of such transactions and the impact such reorganization may have on U.S. and foreign tax liability and financial condition.

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

As of December 31, 2010, we had net operating loss carryforwards of approximately $77.9 million for U.S. federal tax purposes. These loss carryforwards will expire in varying amounts through 2030. To the extent these net operating loss carryforwards are available, we intend to use them to reduce the corporate income tax liability associated with our operations. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. As a result, prior or future changes in

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ownership could put limitations on the availability of our net operating loss carryforwards. In addition, our ability to utilize the current net operating loss carryforwards might be further limited by the issuance of common stock in the future. To the extent our use of net operating loss carryforwards is significantly limited, our income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards, which could result in lower profits.

We have determined that we have experienced multiple ownership changes under Section 382. We have estimated that approximately $24.7 million of federal net operating losses can be utilized in the future based on limitations that we have calculated under Section 382. We are currently analyzing alternative positions and additional factual information that may increase the amount of net operating losses that could subsequently be utilized. To the extent that this additional information becomes available and could increase net operating losses available for use, we will adjust our deferred tax assets accordingly, with a corresponding adjustment to our valuation allowance. We also had non-U.S. net operating loss carryforwards of approximately $30.4 million as of December 31, 2010. As a result of our planned corporate restructuring, there is a significant risk these non-U.S. net operating loss carryforwards may not be utilized.

Risks Related to Regulation

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

We are investing in the research and development of new diagnostic tests to expand our menu of testing options, as well as to develop our next-generation NexGen system, which we anticipate will reduce the need for sample preparation when using our system. Our 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 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.

The 510(k) clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. 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 pre-market approval; however, it may take longer, and 510(k) clearance or pre-market approval may never be obtained. Delays in receipt of, or failure to obtain, clearances or approvals for future products, including tests 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. 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 FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

If third-party payors do not reimburse our customers for the use of our clinical diagnostic 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

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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.

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.

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.

In the United States, the American Medical Association assigns specific Current Procedural Terminology, or CPT, codes, which are necessary for reimbursement of diagnostic tests. Once the CPT code is established, the Centers for Medicare and Medicaid Services establish reimbursement payment levels and coverage rules under Medicaid and Medicare, and private payors establish rates and coverage rules independently. We can not 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 and Medicaid or any third-party payor. Third-party payors may nonetheless choose to reimburse our customers on a per test basis 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 that can be used to return multiple test results.

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, Medicare s current freeze on its clinical laboratory fee schedule may adversely affect the growth of the molecular diagnostics market for patients in the United States who are over 65 or have specific disabilities. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for our products, which in turn, could negatively impact pricing. 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.

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, are required to comply with the federal Quality System Regulation, or the QSR, which covers the procedures and documentation

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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 intend to complete the move of our manufacturing operations, to a new facility in Carlsbad, California in March 2011. Any delay in establishing our manufacturing operations at our new facility or obtaining any required licenses or regulatory approvals for our manufacturing facilities could delay our ability to develop or sell our products or cause us to incur more expenses than currently anticipated in our operating budget.

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;
- the FDA s refusal to grant pending future clearance or pre-market approval for our products;
- 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 either of our FDA-cleared diagnostic tests would be particularly harmful to our business and financial results.

The use of our diagnostic products by our customers is also affected by the Clinical Laboratory Improvement Amendments of 1988, or 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 and 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.

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Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, in the future, the FDA may require more burdensome premarket approval of our system or diagnostic tests rather than the 501(k) clearance process we have used to date and anticipate primarily using in the future. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, financial condition 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 comprehensive health care reform legislation known as the Patient Protection and Affordable Care Act of 2010, 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. The PPACA also imposes significant new taxes on medical device manufacturers that are expected to cost the medical device industry up to $20 billion over the next decade. There are also stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals. Complying with PPACA could significantly increase our costs and adversely affect our business and financial condition.

Our operations will also be impacted 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 Federal Food, Drug and Cosmetic Act, or 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 expect to begin paying the tax in 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. We expect compliance with the Health Care Act to impose significant administrative and financial burdens on us.

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

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

The federal False Claims Act, or 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

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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. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely have a material adverse effect on our business, financial conditions and results of operations.

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 negatively affect our business.

Risks Related to Our Intellectual Property

We rely on third-party license agreements for patents and other technology related to our products. The termination of these agreements could delay or prevent us from being able to commercialize our products and the failure to negotiate new licenses could prevent us from expanding our menu of diagnostic products.

We depend on licenses to certain patents and patent applications that are related to electrochemical detection technology and other technology used in our molecular diagnostic systems and test cartridges. These licenses include both exclusive and non-exclusive arrangements. Many of these exclusive licenses obligate us to use commercially reasonable efforts to commercialize the subject inventions of the licensed patents, and if we fail to meet this obligation, we could lose one or more of those licenses. If, following such an event, any of our licensors were to provide a license to these patents to one or more of our competitors, our ability to compete in the market may be diminished. Furthermore, 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.

The exclusive and non-exclusive licenses expire at various times, corresponding to the subject patents or patent applications, the expirations of which currently range from 2013 to 2028. We expect that we will need to license other technology or patents to commercialize future products, including licenses to additional biomarkers to expand our menu of diagnostic tests. These licenses may not be available to us on commercially reasonable terms, or at all, which could adversely affect our results of operations and growth prospects.

We may incur substantial costs as a result of litigation or other proceedings relating to the protection of our patents and other intellectual property rights and we may be unable to protect our rights to our technology.

If we or any of our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or licensed patents, that third party may ask the court to rule that the patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party s activities do not infringe our patents. In addition, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have recently changed some tests regarding granting patents and assessing the validity of patent claims. As a consequence, issued patents may be found to contain

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invalid claims according to the newly revised and currently evolving standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a re-examination proceeding before the Patent and Trademark Office (PTO), or during litigation, under the revised criteria which make it more difficult to obtain patents.

We may also not be able to detect infringement against our own or in-licensed patents, which may be especially difficult for methods of use. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights.

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, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, therefore we can not 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, and may in the future file, patent applications covering our products or technology similar to ours. 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 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. 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;
- 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.

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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.

We may be infringing on the patent rights of third parties, which could prevent us from selling our current or future products.

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. These third parties and others who may in the future threaten us with such litigation, are or may be better capitalized and have more resources than us. In addition, in order to commercialize certain new or existing tests including our Thrombophilia Risk Test, we may be required to license certain biomarkers or risk that a third party may claim that the use of certain biomarkers in our tests infringes their intellectual properly rights. We have received correspondence in the past bringing to our attention certain patent rights held by third parties and offering to discuss licensing terms to the patents. Some of these letters relate to patents that are important to our products. Independently, we have also identified patents held by third parties that cover one or more of our products or planned products. Although we have taken licenses to numerous such third-party patents, we have also declined to license certain patents in instances where we do not believe our existing products infringe valid claims. A license may not be available to us or any collaborator on acceptable terms, or at all, which could potentially prevent us from selling our current products or developing new tests. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away. Furthermore, such litigation is costly and could affect our results of operations and divert the attention of managerial and technical personnel.

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 144 issued U.S. and foreign patents which we own directly or for which we are the exclusive licensee and that expire between 2013 and 2021. 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 can not 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

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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 can not 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.

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. In addition, Congress is currently considering legislation that would change provisions of the patent law. We cannot predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents or the patents and applications of our collaborators and licensors. The patent situation in the medical device and disease diagnostic fields outside the United States is even more uncertain.

Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents;
- we may not be able to identify potential infringers of our technology due in part to the large number of competitors in the field;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges by third parties;
- the claims of our issued patents or patent applications when issued may not cover our device or product candidates;
- there may be dominating patents relevant to our product candidates of which we are not aware;
- there may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware;
- the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States; and
- we may not develop additional proprietary technologies that are patentable.

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

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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 be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in our industry, we employ individuals who were previously employed at other molecular diagnostics or medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Common Stock

Future sales of our common stock may depress our share price.

As of December 31, 2010, we have 11,728,233 shares of our common stock outstanding. Sales of a number of common shares in the public market could cause the market price of our common stock to decline. In addition, our 2010 Plan provides for annual increases in the number of shares available for issuance under the plan. We may also sell additional common stock in subsequent public offerings, which may adversely affect market prices for our common stock.

We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may adversely affect our operating results, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause investors to lose confidence in our operating results and in the accuracy of our financial reports and could have a material adverse effect on our business and on the price of our common stock.

As a public company in the United States, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Our first report on compliance with Section 404 is expected to be in connection with our financial statements for the year ending December 31, 2011. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting. Our independent registered public accounting firm s audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of our

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internal control over financial reporting. Accordingly, no such opinion was expressed. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate. Even after we develop these new procedures additional weaknesses in our internal control over financial reporting may be discovered. In order to fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff and/or to engage a third party consulting firm to assist in risk assessment, documentation and testing of controls. In addition, in the process of evaluating our internal control over financial reporting we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities such as the SEC or NASDAQ and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we or our auditors are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404 we may be subject to sanctions or investigations by regulatory authorities such as the SEC or NASDAQ and we could lose investor confidence in the accuracy and completeness of our financial reports, which would have a material adverse effect on our business and on the price of our common stock and our ability to access the capital markets.

Furthermore, as a public company listed in the United States, we will incur significant additional 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 NASDAQ, may increase 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 notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We currently intend to invest our future earnings, if any, to fund the development and growth of our business. In addition, our credit facility restricts our ability to pay dividends. The payment of dividends will be at the discretion of our board of directors and will depend on 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 any debt agreements we may enter into and other factors our board of directors may deem relevant. If we do not pay dividends, your ability to achieve a return on your investment in our company will depend on any future appreciation in the market price of our common stock. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our holders have purchased their common stock.

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Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, 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 only remove our directors for cause;
- establish a classified board of directors, such that not all members of the board of directors may be elected at one time;
- authorize our board of directors to issue without stockholder approval up to 100,000,000 shares of common stock, that, if issued, would dilute our stock ownership and could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- authorize our board of directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the board of directors that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Item 1B. UNRESOLVED STAFF COMMENTS

None

Item 2. PROPERTIES

We currently operate from two facilities located in Pasadena, California and Carlsbad, California. Our Pasadena manufacturing facility approximates 8,400 square feet. The lease on our Pasadena manufacturing facility expires in July 2011. In July 2010, we moved our headquarters to a new facility in Carlsbad, California and began the transfer of our manufacturing operations to this plant. The move will be completed in March 2011.

We do not own any real property. We believe that our leased facilities are adequate to meet our needs for the foreseeable future.

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Item 3. LEGAL PROCEEDINGS

We are from time to time subject to various claims and legal actions during 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. REMOVED AND RESERVED

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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.

Period from May 28, 2010 to December 31, 2010:

	High	Low
Second Quarter	$ 6.00	$ 4.02
Third Quarter	$ 5.15	$ 3.27
Fourth Quarter	$ 5.20	$ 2.97

Stock Performance Graph

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

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Stockholders

The last reported sale price of common stock on March 1, 2011 as reported on the Nasdaq Global Market was $4.28. As of March 1, 2011, there were 9,131 holders of record of 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.

Use of Proceeds from Public Offering of Common Stock

On June 3, 2010, we closed our initial public offering, in which we sold 4,600,000 shares of common stock at a price to the public of $6.00 per share. The aggregate offering price for shares sold in the offering was $27.6 million. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-165562), which was declared effective by the SEC on May 28, 2010. The offering commenced as of May 28, 2010 and did not terminate before all of the securities registered in the registration statement were sold. Piper Jaffray acted as sole book-running manager for the offering. William Blair & Company and ThinkEquity LLC acted as co-managers of the offering. There were no selling stockholders in the offering. We raised approximately $22.6 million in net proceeds after deducting underwriting discounts and commissions of $1.9 million and other offering expenses of $3.0 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on June 1, 2010 pursuant to Rule 424(b). We invested the funds received in registered money market funds.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data relates to GenMark and its consolidated subsidiaries. The selected consolidated statement of operations data presented below of GenMark for the year ended December 31, 2010 and Osmetech plc for the years ended December 31, 2009 and 2008 and the selected consolidated balance sheet data of GenMark as of December 31, 2010 and Osmetech plc as of December 31, 2009 have been derived from the audited consolidated financial statements of GenMark, which have been prepared in accordance with U.S. GAAP, included elsewhere in this Form 10-K.

The selected consolidated financial statements of operations data of Osmetech plc presented below for the year ended December 31, 2007 and the selected consolidated balance sheet data of Osmetech plc as of December 31, 2008 have been derived from audited consolidated financial statements of Osmetech plc, not included in this Form 10-K, which have been prepared in accordance with U.S. GAAP.

The selected consolidated financial statement of operations data presented below for the year ended December 31, 2006 and the selected consolidated balance sheet data as of December 31, 2007 and 2006 have been derived from unaudited consolidated financial information, not included in this Form 10-K, and have been prepared by GenMark 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 Management s Discussion and Analysis of Financial Condition and Results of Operations and with the consolidated financial statements and unaudited condensed consolidated financial statements of GenMark and related notes included elsewhere in this prospectus.

	2010	2009	2008	2007	2006
Consolidated Statements of Operations Data:					
Revenue:					
Product sales	$ 2,340,996	$ 910,527	$ 559,592	$ 234,099	$ 50,500
License and other revenue	163,872	87,889	87,500	107,500	41,062
Total revenue	2,504,868	998,416	647,092	341,599	91,562
Cost of sales	4,377,701	4,332,299	3,237,869	2,624,589	2,331,430
Gross loss	(1,872,833)	(3,333,883)	(2,590,777)	(2,282,990)	(2,239,868)
Operating expenses:					
Sales and marketing	4,282,521	3,181,762	3,393,665	2,220,098	905,962
Research and development	6,522,112	5,633,717	13,423,679	12,554,236	10,606,562
General and administrative	7,353,802	8,288,762	9,632,708	8,895,796	9,781,509
Total operating expenses	18,158,435	17,104,241	26,450,052	23,670,130	21,294,033
Loss from operations	(20,031,268)	(20,438,124)	(29,040,829)	(25,953,120)	(23,533,901)
Other (expense) income:					
Foreign exchange (loss) gain	(1,110)	303,523	504,921		
Interest income (expense)	(582)	33,222	420,011	1,715,211	522,293
Therapeutic Discovery Credit	1,645,292				
Total other income	1,643,600	336,745	924,932	1,715,211	522,293
Loss before income taxes	(18,387,668)	(20,101,379)	(28,115,897)	(24,237,909)	(23,011,608)
(Provision) benefit for income taxes	(15,324)	138,770	(246,736)	300,214	231,637
Net loss from continuing operations	$ (18,402,992)	$ (19,962,609)	$ (28,362,633)	$ (23,937,695)	$ (22,779,971)
Net loss per common share from continuing operations (basic and diluted)	$ (1.88)	$ (4.41)	$ (28.13)	(27.13)	$ (31.67)
Weighted average shares used in net loss per common share	9,796,588	4,526,758	1,008,386	882,325	719,378

	As of December 31,				
	2010	2009	2008	2007	2006
Balance Sheet Data:					
Cash and cash equivalents	$ 18,329,079	$ 16,482,818	$ 8,822,458	$ 27,619,715	$ 13,874,798
Total assets	24,925,509	19,333,477	15,175,215	33,233,621	26,718,736
Long-term liabilities	612,932	795,334	769,237	720,355	339,144
Total liabilities	3,858,091	4,008,659	5,237,946	3,265,933	8,359,361
Accumulated deficit	(144,492,881)	(126,089,889)	(106,127,280)	(77,764,647)	(88,309,444)
Total stockholders equity	21,067,418	15,324,818	9,937,269	29,967,688	18,359,375

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Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

You should read the following in conjunction with the Selected Consolidated Financial Information and the consolidated financial statements of GenMark and the related notes thereto that appear elsewhere in this 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 Risk Factors elsewhere in this prospectus. See also Special Note Regarding Forward Looking Statements included elsewhere in this filing.

Overview

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware in February 2010 and had no operations prior to its initial public offering which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of (i) the issuance of common stock of GenMark to the former shareholders of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a subsidiary controlled by GenMark, and the former shareholders of Osmetech began to hold shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization.

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 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 30 minutes of receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports up to 24 independent test cartridges, which can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are hospitals and reference laboratories.

We have developed four diagnostic tests for use with our XT-8 system and expect to expand this test menu by introducing two to four new tests annually. Our Cystic Fibrosis Genotyping Test, which detects pre-conception risks of cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual s ability to metabolize the oral anticoagulant warfarin, and our Thrombophilia Risk Test, which detects an individual s increased risk of blood clots, have received FDA clearance. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed a Respiratory Viral Panel Test, which detects the presence of major respiratory viruses and is labeled for investigational use only, or IUO. We intend to seek FDA clearance for our Respiratory Viral Panel Test in 2011. We also have a pipeline of several additional potential products in different stages of development or design, including diagnostic tests for an individual s sensitivity to Plavix, a commonly prescribed anti-coagulant, and for mutations in a gene known as K-ras, which is predictive of an individual s response rates to certain prescribed anti-cancer therapies.

We are also developing our next-generation platform, the NexGen system. We are designing the NexGen system to integrate DNA amplification with our eSensor detection technology to enable technicians using the NexGen system to be able to place a raw or minimally prepared patient sample 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 years ended December 31, 2010, 2009 and 2008 were approximately $18.4 million, $20.0 million and $28.4 million, respectively. As of December 31, 2010, we had an accumulated deficit of $144.5 million. Our operations to date have been funded principally through sales of capital stock and sales of our previous businesses. We expect to incur increasing expenses over the next several years, principally to develop additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Financial Results Overview

Revenue

Revenue from continuing operations includes product sales, principally of our eSensor Cystic Fibrosis Genotyping Test and, to a lesser extent, our Warfarin Sensitivity Test, for use with our XT-8 system and our predecessor eSensor 4800 System. We primarily place our XT-8 system with customers through a reagent rental agreement, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years. We also offer our XT-8 system for sale, however, for the year ended December 31, 2010, we had sold only ten XT-8 systems to customers which included the sale of thirteen analyzers.

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 on both reagent rental agreements and system sales of our current XT-8 system and our next-generation NexGen system that is currently under development. We plan to expand our base of customers and systems as well as adding more tests for use with our 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 and our predecessor eSensor 4800 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, and amortization of licenses related to our test cartridges.

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 costs of sales to increase as we place additional XT-8 systems and manufacture and sell an increasing menu of accompanying diagnostic tests.

We manufacture our test cartridges in our facility and have significant capacity for expansion. This underutilized capacity results in a high cost of sales relative to revenue, resulting in a gross loss. We believe cost of sales as a percentage of revenue will decrease as our sales of test cartridges grow.

Sales and Marketing Expenses

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

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Research and Development Expenses

Research and development expenses primarily include expenses related to the development of our XT-8 system and its predecessor eSensor 4800 System, including the detection system and the test cartridges. These expenses also included clinical study expenses incurred in the process of preparing for FDA clearance for these systems and test cartridges. The expenses primarily consisted of salaries, benefits, share-based compensation costs, outside design and consulting services, laboratory supplies, contract research organizations, 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 more advanced systems and increase the development of new tests for our XT-8 system.

General and Administrative Expenses

Our general and administrative expenses include our executive, accounting and finance, information technology, legal, intellectual property, human resource and investor relations departments. These expenses consist primarily of salaries, benefits, share-based compensation costs, independent auditor costs, legal fees, consultants, travel, insurance, relocation, and public company expenses such as stock transfer agent fees and listing fees for AIM and 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. Exchange gains and losses also 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.

Interest Income (expense)

Interest income (expense) includes interest earned on our cash and cash equivalents less interest accrued on other liabilities.

Benefit (Provision) for Income Taxes

We account for income taxes in accordance with ASC 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.

Critical Accounting Polices 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.

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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 test cartridges. When a system is sold, revenue is generally recognized upon shipment of the unit. 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, we retain the right to access or replace the systems at any time and our customers pay an additional system rental fee for each test cartridge purchased. The reagent rental fee varies based on the monthly volume of test cartridges purchased.

We sell our durable systems and disposable test cartridges through a direct sales force in the United States. Components are individually priced and can be purchased separately or together. The system price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on system and test cartridge sales is recognized upon shipment, 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.

During the year ended December 31, 2010, we sold ten XT-8 systems to customers which included the sale of thirteen analyzers.

Revenue related to royalties received from licenses is recognized evenly over the contractual period to which the license relates. Revenue from service agreements is recognized using the proportional performance method of accounting.

Shipping and handling costs are expensed as incurred and included in cost of product sales. In those cases where we bill shipping and handling costs to customers, the amounts billed are classified as revenue.

Property and Equipment

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 previously the predecessor eSensor 4800 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 shortened if circumstances dictate a change.

Machinery and laboratory equipment	-	3 - 5 years
Systems at customer location	-	3 years
Office equipment	-	2 - 4 years
Leasehold improvements	-	over the shorter period of the life of the lease or the useful economic life of the asset

During 2009, our estimate of the useful life of our systems was changed from five years to three years. This estimate was revised due to a change in our strategy to accelerate the development of our next-generation system and did not have a significant impact on the results for the period.

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 such assets may not be recoverable. If impairment is indicated, we write down the carrying value of the asset to the estimated fair value. This fair value is usually determined based on an estimate of future discounted cash flows. The primary cause for us to consider systems at customer locations for impairment is evidence that customers are not ordering the minimum quantities set forth in their reagent rental agreement. For impairment of systems at customers locations, which are assessed separately for each customer, we analyze the recoverability based on historical and estimated future sales of test cartridges to each customer. In

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the year ended December 31, 2010, no impairment charges were recorded. In the year ended December 31, 2009, we recorded an impairment against systems of $865,389, which was recorded within cost of sales ($665,718), sales and marketing ($129,712) and research and development ($69,959).

Share-Based Compensation

We have granted our options with an exercise price equal to the closing price of GenMark s 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.

Expected Volatility. Expected volatility represents the volatility in our stock price expected over the expected term of the option.

Expected Dividend. The Black-Scholes valuation 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 valuation method is based on published government rates in effect at the time of grant for periods corresponding with the expected term of option.

Estimated Forfeitures. The estimated forfeiture rate is determined based on our historical forfeiture rates. We will monitor actual expenses and periodically update the estimate.

Valuation. Our board of directors determined the fair value of our common stock to be equivalent to the closing prices on the NASDAQ Global Market. GenMark s shares trade on the NASDAQ on a daily basis and reflect prices that investors are willing to pay for GenMark s shares.

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 subject to income taxes in both the United States and the United Kingdom. Significant judgments and estimates are required in determining the consolidated income tax expense.

We believe that it is more likely than not that the benefit from certain U.S. federal and U.S. state net operating loss carryforwards will not be realized. In recognition of this risk, we have provided a valuation allowance of approximately $13.1 million on the deferred tax assets relating to these net operating loss carryforwards and other deferred tax assets. If our assumptions change and we determine we will be able to realize these net operating losses, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets at December 31, 2010 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 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.

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Recent Accounting Pronouncements

In October 2009, authoritative guidance was provided on revenue arrangements with multiple deliverables. The guidance amended the accounting standards for multiple deliverable revenue arrangements to: (i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated; (ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and (iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

Arrangements that contain multiple deliverables include sales of systems and test cartridges. These are accounted for as separate units of accounting if the following criteria are met: (i) the delivered item or items have value to the customer on a standalone basis and (ii) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. The Company considers a deliverable to have standalone value if the item is sold separately or if the item could be resold by the customer. The Company s revenue arrangements generally do not include a right of return relative to delivered products. The Company sold its first systems in 2010. The Company elected to early adopt the new accounting guidance because it is able to meet the new separation criteria and has applied it to all applicable revenue arrangements entered into or materially modified beginning January 1, 2010.

Results of Operations 2010 compared to 2009

Revenue

Revenue increased $1.5 million, or 151%, to $2.5 million for the year ended December 31, 2010 compared to $998,000 for the year ended December 31, 2009. Product sales increased $1.4 million, or 157%, to $2.3 million for the year ended December 31, 2010 compared to $911,000 for the year ended December 31, 2009. License and other revenue increased $76,000 to $164,000, or 86%, for the year ended December 31, 2010, due to increased service revenue, compared to $88,000 for the year ended December 31, 2009. The increase in product revenue was primarily driven by increased reagent revenues as well as system sales and other product revenue and was due to an increase in our installed base of systems and an expanded menu of tests available for sale. License revenue increased predominantly due to a collaboration agreement executed in conjunction with a clinical trial for Warfarin.

Cost of Sales and Gross Loss

Cost of sales increased $46,000, or 1%, to $4.4 million for the year ended December 31, 2010 compared to $4.3 million for the year ended December 31, 2009. The increase was primarily due to the increase in reagent and system shipments. Gross loss decreased $1.5 million or 44% to $1.9 million for the year ended December 31, 2010 compared to a gross loss of $3.3 million in 2009. The decrease was due to higher revenues in 2010 but not a corresponding increase in cost of sales due to increased capacity utilization.

Sales and Marketing

Sales and marketing expense increased $1.1 million, or 35% to $4.3 million for the year ended December 31, 2010, compared to $3.2 million for the year ended December 31, 2009. The increase was driven by higher payroll costs. We built our direct sales force during 2010 and expect these costs to increase during 2011 and beyond.

Research and Development

Research and development expense increased $888,000, or 16%, to $6.5 million for the year ended December 31, 2010 compared to $5.6 million for the year ended December 31, 2009. The increase was due to higher payroll costs, including relocation and recruiting fees and increased usage of project supplies.

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General and Administrative

General and administrative expense decreased $935,000, or 11%, to $7.4 million for the year ended December 31, 2010 compared to $8.3 million for year ended December 31, 2009. The decline was due to reduced facility costs and professional fees offset by relocation costs related to our move from Pasadena to Carlsbad.

Foreign Exchange

We incurred a foreign exchange loss for the year ended December 31, 2010 of $1,000 as compared to a gain of $304,000 for the year ended December 31, 2009. The gain was due to the settlement of U.S. dollar liabilities during the year as the U.S. dollar weakened against the British pound combined with the benefit of maturing U.S. dollar forward contracts which were held by us during the period. There were few foreign exchange transactions during 2010.

Interest Income (Expense)

Interest income (expense), declined $34,000 to $1,000 net interest expense for the year ended December 31, 2010 compared to $33,000 net interest income for the year ended December 31, 2009, due to lower cash balances during the year as well as increased expense on a tax liability.

Other Income (Therapeutic Discovery Credit)

We recorded other income related to the Therapeutic Discovery Credit of $1.6 million for the year ended December 31, 2010. In July 2010, we applied for certification of qualified investments eligible for credits and grants under the qualifying therapeutic discovery project program for the years ended December 31, 2009 and December 31, 2010. The $1.6 million in grant applications were for expenses incurred in 2010 and 2009. The company received $561,000 for 2009 expenses and $1.1 million for 2010 expenses.

These development projects included the NexGen system (formerly the AD-8 system), K-ras mutation cancer treatment, Plavix Sensitivity Drug, Warfarin Sensitivity Test, Thrombophilia Risk Test, Respiratory Viral Panel and Cystic Fibrosis Genotyping. In November 2010, we were notified that we were awarded a total of $1.6 million under the program. As of December 31, 2010, the Company recorded the $1.6 million tax credit as an Other Current Assets on the Balance Sheet with a corresponding credit to Other Income on the Consolidated Statement of Operations.

Benefit (Provision) for Income Taxes

A tax provision of $15,000 was recorded for the year ended December 31, 2010, compared to a tax benefit of $139,000 for the year ended December 31, 2009. The amount of the 2010 tax provision consists primarily of state income taxes. During 2009, a benefit was recognized relating to a carry-back of tax losses to prior years following the enactment of the Worker, Homeownership and Business Assistance Act of 2009.

Results of Operations 2009 compared to 2008

Revenue

Revenue increased $351,000, or 54%, to $998,000 for the year ended December 31, 2009 compared to $647,000 for year ended December 31, 2008. Product sales increased $351,000 or 63% to $911,000 for the year ended December 31, 2009 compared to $560,000 for the year ended December 31, 2008. License revenue of $88,000 for the year ended December 31, 2009 was equivalent compared to the year ended December 31, 2008. License revenue was predominantly attributable to annual maintenance and minimum royalties from existing licensees.

Product sales consisted solely of test cartridge sales, which are only available for purchase through reagent rental agreements or through negotiated purchase orders following purchase of an XT-8 system. The increase in

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revenue for 2009 was driven by sales of our Cystic Fibrosis Genotyping Test which replaced the predecessor Cystic Fibrosis Carrier Detection Test following FDA clearance of the test in July 2009. Revenue growth was hampered during this period by the lack of sufficient capital and the use of a distributor-based sales effort instead of a direct sales force for a major portion of the year ended December 31, 2009. Distributors generally do not dedicate substantial time to educate customers and monitor the evaluation of high technology new products which we believe adversely impacted our sales.

Cost of Sales

Cost of sales increased $1.1 million, or 34%, to $4.3 million for the year ended December 31, 2009 compared to $3.2 million for the year ended December 31, 2008. The increase was due to $666,000 in impairment charges for systems, and $549,000 in impairment charges for intangibles, partially offset by lower expenses for manufacturing support and temporary labor as production processes improved.

Sales and Marketing

Sales and marketing expense decreased $212,000, or 6% to $3.2 million for the year ended December 31, 2009, compared to $3.4 million for the year ended December 31, 2008. The decrease was driven by lower salaries and travel expenses partially offset by $381,000 for a one-time market research study in 2009, relocation of the newly hired commercial team and increased depreciation of XT-8 systems used in marketing evaluations. During 2009, we changed our estimate of the useful life of systems used for marketing purposes from five years to three years, which increased our depreciation for 2009 compared to 2008 by $38,000, and we recorded an impairment charge of $130,000 for certain demonstration units.

Research and Development

Research and development expense declined $7.8 million, or 58%, to $5.6 million for the year ended December 31, 2009 compared to $13.4 million for the year ended December 31, 2008. The decline was due to a substantial reduction in research and development headcount and expenses in 2009 after the completion of the XT-8 system development. We also consolidated our Rockland, Massachusetts and Menlo Park, California research facilities into our headquarters in Pasadena, California.

General and Administrative

General and administrative expense decreased $1.3 million, or 14%, to $8.3 million for the year ended December 31, 2009 compared to $9.6 million for year ended December 31, 2008. The decline was due to costs during 2008 related to our fund raising activities.

Foreign Exchange

Foreign exchange gain declined $201,000, or 40%, to $304,000 for the year ended December 31, 2009 compared to $505,000 for the year ended December 31, 2008. The gain was due to the settlement of U.S. dollar liabilities during the year as the U.S. dollar weakened against the British pound combined with the benefit of maturing U.S. dollar forward contracts which were held by us during the period.

Interest Income

Interest income declined $387,000, or 92% to $33,000 for the year ended December 31, 2009 compared to $420,000 for the year ended December 31, 2008, due to lower cash balances and declining interest rates in 2009.

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Benefit (Provision) for Income Taxes

A tax benefit of $139,000 was recorded for the year ended December 31, 2009, compared to a tax provision of $247,000 for the year ended December 31, 2008. During 2009, a benefit was recognized relating to a carry-back of tax losses to prior years following the enactment of the Worker, Homeownership and Business Assistance Act of 2009. During 2008, a tax provision was recorded due to amendments made to the research and development tax credit claimed in prior periods.

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock, proceeds from sale of a business and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability.

At December 31, 2010, we had $18.9 million of working capital, including $18.3 million in cash and cash equivalents. Net cash used in operations increased $3.5 million to $18.9 million for the year ended December 31, 2010 compared to $15.4 million for the year ended December 31, 2009, primarily due to the recording of the $1.6 million Therapeutic Discovery Credit receivable in 2010, impairment losses recorded in 2009 and a build-up of inventory due to the relocation of the manufacturing facility in 2010. Net cash used in investing activities increased $801,000 to $1.9 million for the year ended December 31, 2010 compared to $1.1 million for the year ended December 31, 2009 due to more purchases of capital assets, primarily XT-8 systems used for reagent rental programs and leasehold improvements for our new manufacturing facility.

Net cash provided by financing activities decreased $1.5 million for the year ended December 31, 2010 to $22.6 million, compared to $24.1 million for the year ended December 31, 2009 due to a slightly smaller fund raise in 2010 as compared to 2009.

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 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of December 31, 2010) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. As of December 31, 2010, the Company had not drawn any funds under this loan and security agreement.

In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased by $1 million to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans

An additional loan was made available under the amended loan and security agreement for up to $1 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of March 11, 2011, the Company had no outstanding loans on the line of credit and had drawn $2 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original term loan. The loan bears an interest rate of 7.5%.

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We believe that our current cash and cash equivalents, our borrowing capacity, and the proceeds from our initial public offering will be sufficient 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, expand our research and development, commercialization and manufacturing activities. The amount of additional capital we may need to raise depends on many factors, including:

- the level of revenues and the rate of revenue growth;
- the level of expenses required to expand our sales and marketing activities;
- the number of systems placed on a reagent rental basis;
- the level of research and development investment required to maintain and improve our technology;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments;
- our need to acquire or license complementary technologies or acquire complementary businesses; and
- changes in regulatory policies or laws that affect our operations.

We can not be certain that additional capital will be available when and as 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 the 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, when 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. When 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.

Contractual Obligations

As of December 31, 2010, we had contractual obligations relating to our facilities leases as follows:

		Payments due by period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Operating lease obligations (1)	$ 4,703,084	$ 992,471	$ 1,746,464	$ 1,253,871	$ 710,278

(1) Included in these amounts are our facilities leases. 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 exit certain contracts or if we enter into additional operating leases.

In addition to the obligations in the table above, we periodically purchase systems from a contract manufacturer. In order to guarantee delivery, we issue purchase orders each 90 day period for delivery of systems during that period. At December 31, 2010, we had outstanding purchase orders for $27,860 worth of systems.

Additionally, approximately $487,000 of unrecognized tax benefits, including accrued interest and penalties of $105,000, have been recorded as liabilities and we are uncertain as to if or when such amounts may be settled.

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In November 2009, we renegotiated our lease on our 25,000 square foot headquarters facility in Pasadena, California that lowered our rent and accelerated the termination of that lease to June 30, 2010.

In March 2008, we exercised our option to extend the operating lease of the premises at our approximately 8,400 square-foot manufacturing facility in Pasadena, California, for a three-year period from August 1, 2008 until July 31, 2011 at a rental cost of $21,558 per month. On February 8, 2010, we entered into a seven-year and seven-month lease for a new 31,098 square foot facility in Carlsbad, California. 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 158,733 rentable square feet. Monthly rental payments are $48,260 and increases 3% annually. We also pay our pro-rata share of the building and project maintenance, property tax, management and other costs subject to certain limitations. We have paid a $55,000 security deposit and provided a $500,000 standby letter of credit as security for the future rent as well as for up to $2.0 million in landlord funded tenant improvements. The lease also provides for expansion rights and rights of first refusal for expansion within our building, subject to certain limitations.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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. 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, in the future we may 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, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Foreign Currency Exchange Risks

Substantially all of our operating facilities are located within the United States. Our UK subsidiary previously used the British Pound as its functional currency; however, it is no longer an operating entity. Virtually all of our revenues are based in the United States. A small portion of our expenses, relating to our corporate office, were transacted in British pounds. Our U.S. based subsidiaries use the U.S. dollar as their functional currency.

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Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Board of Directors and Stockholders of

GenMark Diagnostics, Inc.

We have audited the accompanying consolidated balance sheet of GenMark Diagnostics, Inc. and subsidiaries (the Company) (formerly Osmetech plc and subsidiaries) as of December 31, 2010, and the related consolidated statements of operations, comprehensive loss, stockholders equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on the consolidated financial statements 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 the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2010, and the results of its operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE, LLP

San Diego, CA

March 11, 2011

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To the Board of Directors and Stockholders of

Osmetech plc

London, United Kingdom

We have audited the accompanying consolidated balance sheet of Osmetech plc and subsidiaries (the Company) as of December 31, 2009, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for each of the two years in the period ended December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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 financial position of Osmetech plc and subsidiaries as of December 31, 2009, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE LLP

St. Albans, United Kingdom

March 19, 2010

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GenMark Diagnostics, Inc.

Consolidated Balance Sheets as of December 31, 2010 and 2009

	As of December 31, 2010	2009
Current assets		
Cash and cash equivalents	$ 18,329,079	$ 16,482,818
Accounts receivable net	677,648	169,842
Inventories net	896,809	136,967
Other current assets	2,193,160	992,181
Total current assets	22,096,696	17,781,808
Property and equipment net	2,702,478	1,381,618
Intangible assets net	70,980	170,051
Other long-term assets	55,355	
Total assets	$ 24,925,509	$ 19,333,477
Current liabilities		
Accounts payable	$ 823,242	$ 1,504,905
Accrued compensation	1,171,989	822,388
Other current liabilities	1,249,928	886,032
Total current liabilities	3,245,159	3,213,325
Other non-current liabilities	612,932	795,334
Total liabilities	3,858,091	4,008,659
Commitments and contingencies See note 6		
Stockholders equity		
Ordinary shares, £0.23 ($0.3634 as of December 31, 2009) par value; -0- and 7,101,928 shares issued and outstanding as of December 31, 2010 and December 31, 2009, respectively		2,573,857
Deferred shares, £0.0099 ($0.01709 as of December 31, 2009) par value; -0- and 689,478,300 shares issued and outstanding as of December 31, 2010 and December 31, 2009, respectively		11,780,709
Common stock, $.0001 par value; 100,000,000 authorized; 11,728,233 and -0- issued and outstanding as of December 31, 2010 and December 31, 2009, respectively	1,172	
Preferred stock, $0.0001 par value; 5,000,000 authorized, none issued		
Additional paid-in capital	166,009,084	127,475,450
Accumulated deficit	(144,492,881)	(126,089,889)
Accumulated other comprehensive loss	(449,957)	(415,309)
Total stockholders equity	21,067,418	15,324,818
Total liabilities and stockholders equity	$ 24,925,509	$ 19,333,477

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

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GenMark Diagnostics, Inc.

Consolidated Statements of Operations

For the Years ended December 31, 2010, 2009 and 2008

	Year ended December 31,		
	2010	**2009**	**2008**
Revenue			
Product revenue	$ 2,340,996	$ 910,527	$ 559,592
License and other revenue	163,872	87,889	87,500
Total revenue	2,504,868	998,416	647,092
Cost of sales	4,377,701	4,332,299	3,237,869
Gross loss	(1,872,833)	(3,333,883)	(2,590,777)
Operating expenses			
Sales and marketing	4,282,521	3,181,762	3,393,665
Research and development	6,522,112	5,633,717	13,423,679
General and administrative	7,353,802	8,288,762	9,632,708
Total operating expenses	18,158,435	17,104,241	26,450,052
Loss from operations	(20,031,268)	(20,438,124)	(29,040,829)
Other income			
Foreign exchange gain (loss)	(1,110)	303,523	504,921
Interest income (expense)	(582)	33,222	420,011
Therapeutic discovery credit	1,645,292		
Total other income	1,643,600	336,745	924,932
Loss before income taxes	(18,387,668)	(20,101,379)	(28,115,897)
(Provision) benefit for income taxes	(15,324)	138,770	(246,736)
Net loss	$ (18,402,992)	$ (19,962,609)	$ (28,362,633)
Net loss per share, basic and diluted	$ (1.88)	$ (4.41)	$ (28.13)
Weighted average number of shares outstanding	9,796,588	4,526,758	1,008,386
Consolidated Statements of Comprehensive Loss For the Years ended December 31, 2010, 2009 and 2008			
Net loss	$ (18,402,992)	$ (19,962,609)	$ (28,362,633)
Foreign currency translation adjustment	(34,648)	(93,682)	(1,157,707)
Comprehensive loss	$ (18,437,640)	$ (20,056,291)	$ (29,520,340)

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

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GenMark Diagnostics, Inc.

Consolidated Statements of Stockholders Equity

For the Years ended December 31, 2010, 2009 and 2008

	Ordinary Shares		Deferred Stock					Accumulated other		
	Shares	Par value	Shares	Par value	Common Stock Shares	Par value	Additional paid-in capital	compreh-ensive income (loss)	Accumulated deficit	Total
Balance January 1, 2008	203,056,639	$ 360,439	689,478,300	$ 11,780,709		$	$ 94,755,107	$ 836,080	$ (77,764,647)	$ 29,967,688
Share-based compensation related to stock options							(256,219)			(256,219)
Exercise of share options	60,000	119					22,840			22,959
Issuance of ordinary shares, net of offering expenses	688,490,518	1,006,504					8,716,677			9,723,181
Foreign currency translation adjustment								(1,157,707)		(1,157,707)
Net loss									(28,362,633)	(28,362,633)
Balance December 31, 2008	891,607,157	$ 1,367,062	689,478,300	$ 11,780,709		$	$ 103,238,405	$ (321,627)	$ (106,127,280)	$ 9,937,269
Share-based compensation related to share options							1,311,033			1,311,033
Issuance of ordinary shares, net of offering expenses	741,836,194	1,206,795					22,926,012			24,132,807
Foreign currency translation adjustment								(93,682)		(93,682)
Net loss									(19,962,609)	(19,962,609)
Balance December 31, 2009	1,633,443,351	$ 2,573,857	689,478,300	$ 11,780,709		$	$ 127,475,450	$ (415,309)	$ (126,089,889)	$ 15,324,818
Share-based compensation related to share options							1,552,871			1,552,871
Exercise of share options	4,964,403	7,482								7,482
Reorganization	(1,638,407,754)	(2,581,339)	(689,478,300)	(11,780,709)	7,128,233	712	14,361,336			
Issuance of common stock, net of offering expenses					4,600,000	460	22,619,427			22,619,887
								(34,648)		(34,648)

Foreign currency translation adjustment								
Net loss							(18,402,992)	(18,402,992)
Balance December 31, 2010	$	$	11,728,233	$ 1,172	$ 166,009,084	$ (449,957)	$ (144,492,881)	$ 21,067,418

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

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GenMark Diagnostics, Inc.

Consolidated Statements of Cash Flows

For the Years Ended December 31, 2010, 2009 and 2008

	Year ended December 31,		
	2010	**2009**	**2008**
Cash flows from operating activities			
Net loss	$ (18,402,992)	$ (19,962,609)	$ (28,362,633)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	1,063,311	1,569,074	1,157,655
Loss from disposal of property and equipment		8,462	31,335
Impairment losses		1,505,642	
Share-based compensation	1,552,871	1,311,033	(256,219)
Changes in operating assets and liabilities:			
Accounts receivable	(507,806)	(51,068)	(21,056)
Inventories	(651,130)	1,227,383	(736,121)
Other current assets	(1,404,305)	315,985	(172,491)
Accounts payable	(1,058,342)	(857,307)	1,365,330
Accrued and other current liabilities	547,670	(510,168)	825,595
Net cash used in operating activities	(18,860,723)	(15,443,573)	(26,168,605)
Cash flows from investing activities			
Proceeds from the sale of property and equipment and intangible assets		10,000	160,000
Purchases of property and equipment	(1,859,877)	(1,068,671)	(1,592,715)
Net cash used in investing activities	(1,859,877)	(1,058,671)	(1,432,715)
Cash flows from financing activities			
Proceeds from the issuance of ordinary shares and common stock	27,600,000	24,132,807	9,723,182
Costs incurred in conjunction with initial public offering	(4,990,937)		
Proceeds from stock option exercises	4,734		22,959
Net cash provided by financing activities	22,613,797	24,132,807	9,746,141
Effect of foreign exchange rate changes	(46,936)	29,797	(942,078)
Net increase (decrease) in cash and cash equivalents	1,846,261	7,660,360	(18,797,257)
Cash and cash equivalents Beginning of year	16,482,818	8,822,458	27,619,715
Cash and cash equivalents End of year	$ 18,329,079	16,482,818	$ 8,822,458
Supplemental cash flow disclosures:			
Cash received for income taxes	$ 5,049	$ 181,162	$ 391,086
Cash received for interest	$ 25,025	$ 33,222	$ 420,011
Noncash investing and financing activities:			
Reclassification of deposits on systems in other current assets, and inventory to property and equipment in 2010 and 2009, respectively	$ 288,962	$ 256,909	
IPO Costs incurred but not paid	$ 103,626		

VAT tax refund related to IPO costs recorded but not received	$	114,450
Transfer of systems from property and equipment into inventory	$	108,712
Fixed asset acquisitions included in accounts payable	$	275,799

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) is a molecular diagnostics company focused on developing and commercializing the Company s proprietary e-sensor technology. On February 12, 2010, the Company was established to serve as the parent company of Osmetech plc (Osmetech) upon a corporate reorganization and initial public offering (IPO). On June 3, 2010, the Company completed an IPO for 4,600,000 shares. Immediately prior to the completion of the IPO, the Company underwent a corporate reorganization whereby the ordinary shares of Osmetech were exchanged by its shareholders for the common stock of the Company on a 230 for 1 basis.

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.

The preferred stock may be issued from time to time in one or more series.

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

Subsequent events have been evaluated through March 11, 2011, being the date that the financial statements were available to be issued.

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 $144,492,881 at December 31, 2010. Cash and cash equivalents at December 31, 2010 were $18,329,079.

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 of up to $4,000,000, 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 (SEC). The Company s operating results for the year ended December 31, 2010 are not necessarily indicative of the results that may be expected for any future periods.

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Principles of Consolidation The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less, at date of purchase, to be cash equivalents. The majority of these funds are held in interest-bearing money market and bank checking accounts. Interest income is recorded on the accrual basis as earned.

Receivables

Accounts receivable consists of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. Prior to 2010, the Company did not reserve or write-off any receivables.

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. This write down is based on management s reviews of inventories on hand, compared to estimated future usage and sales, shelf-life assumptions, and assumptions about the likelihood of obsolescence. During 2009, due to a change in business strategy, the Company changed the intention to sell its systems, and determined that the systems would be placed at customer sites pursuant to reagent rental agreements. Therefore, $256,909 was transferred from inventory to property and equipment-net.

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:

Machinery and laboratory equipment	-	3 5 years
Systems at customer locations	-	3 years
Office equipment	-	2 4 years
Leasehold improvements	-	over the shorter period of the life of the lease or the useful economic life of the asset

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, generally five years. Amortization of licenses begins upon the Company obtaining FDA clearance to sell products containing 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 its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows.

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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 inventories, plant and equipment, intangible assets, certain accrued liabilities related to the Company s former facilities and share-based compensation. Actual results could differ from those estimates.

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. Where applicable, all revenue is stated net of sales taxes and trade discounts.

The Company s XT-8 systems are placed free of charge with customers in exchange for an annual minimum purchase commitment of products from the customer, while the Company retains the right to access or replace the systems at any time. Therefore, the systems remain capitalized on the balance sheet. Revenue from sales of the test cartridges and related products are recognized when the risks and rewards of ownership are transferred to the customer, which is generally at the time of product shipment.

Revenues related to royalties received from licenses are recognized evenly over the contractual period to which the license relates. Services provided are recognized evenly over the contractual period to which the services relate.

Shipping and handling costs are expensed as incurred and included in cost of product sales. 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 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. Because there were no system sales in 2009 or 2008, the product warranty reserve has been zero prior to 2010.

Product warranty reserve activity for the year ended December 31, 2010 is as follows:

	2010
Beginning balance	$
Provisions	25,000
Ending balance	$ 25,000

Research and Development Costs

Research and development costs are expensed as incurred.

Income Taxes

The Company accounts for deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided to reduce deferred tax assets to the amount management believes will, more likely than not, be recovered.

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

Share-Based Compensation

The Company recognizes share-based compensation expense related to share options and warrants issued 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 an accelerated basis to reflect the vesting as it occurs. The share-based compensation expense is recorded in cost 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 life of the option or warrant, the expected volatility and other factors.

Fair Value of Financial Instruments

The carrying amount of the Company s financial instruments, including cash and cash equivalents, accounts receivable and accounts payable approximate their fair values.

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 income in the consolidated balance sheets.

Transactions in foreign currencies were translated into the relevant functional currency at the rate of exchange prevailing at the date of the transaction. Foreign currency transaction gains (losses), which are included in the results of operations, totaled $(1,110), $303,523 and $504,921, for the years ended December 31, 2010, 2009, and 2008, respectively, and relate primarily to transactions denominated in U.S. dollars which were undertaken by Osmetech.

Derivative Financial Instruments

In 2008, derivative financial instruments were used principally in the management of foreign currency and interest rate exposures and were recorded in the consolidated balance sheets at fair value. Derivative instruments not designated as hedges were marked-to-market at the end of 2008 with the results included in results of operations. The effect on earnings was not material. The Company did not use derivative financial instruments in 2010 or 2009.

Net Loss Per Common Share

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

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The computations of diluted net loss per share for the years ended December 31, 2010, 2009 and 2008 did not include the effects of the following options and warrants to acquire ordinary stock which were outstanding as of the end of each year as the inclusion of these securities would have been anti-dilutive.

	Year Ended December 31,		
	2010	2009	2008
Share options	1,107,920	993,214	108,590
Warrants	88,317	220,791	
Restricted Stock	204,115		
	1,400,352	1,214,005	108,590

Segment Information

The Company operates in one reportable segment, and substantially all of the Company s operations and assets are in the United States of America.

Concentration of Risk

The Company had sales to customers representing greater than 10% of the total as follows:

	Year Ended December 31,		
	2010	2009	2008
Customer A	12%		
Customer B		15%	13%
Customer C		12%	23%
Customer D		11%	
Customer E			18%

The Company s XT-8 system is manufactured by a single source supplier that specializes in contract design and manufacturing of electronic and electromechanical devices for medical use.

Comprehensive Income (Loss)

U.S. GAAP requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including accumulated translation adjustments. The Company reports comprehensive income (loss) as a separate component of stockholders equity.

Recent Accounting Pronouncements

In October 2009, authoritative guidance was provided on revenue arrangements with multiple deliverables. The guidance amended the accounting standards for multiple deliverable revenue arrangements to: (i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated; (ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and (iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

Arrangements that contain multiple deliverables include sales of systems and test cartridges. These are accounted for as separate units of accounting if the following criteria are met: (i) the delivered item or items have value to

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the customer on a standalone basis and (ii) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. The Company considers a deliverable to have standalone value if the item is sold separately or if the item could be resold by the customer. The Company s revenue arrangements generally do not include a right of return for delivered products.

The Company sold its first systems in the year ended December 31, 2010. The Company elected to early adopt the new accounting guidance because it is able to meet the new separation criteria and has applied it to all applicable revenue arrangements entered into or materially modified beginning January 1, 2010. The adoption of the new guidance had an immaterial effect on the financial statements and on loss per share for the year ended December 31, 2010.

The adoption of this guidance did not result in a change in the Company s units of accounting or in how the Company allocates arrangement consideration to its units of accounting, as the arrangements to which the new accounting guidance is applicable were first entered into during the year ended December 31, 2010.

3. Intangible assets

Intangible assets, consisting of purchased intellectual property, as of December 31, 2010 and 2009 comprise the following:

	December 31, 2010			December 31, 2009		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Patents and trademarks	$ 438,032	$ (438,032)	$	$ 438,032	$ (438,032)	$
Intellectual property	877,140	(877,140)		877,140	(877,140)	
Licenses	1,251,518	(1,180,538)	70,980	1,251,518	(1,081,467)	170,051
	$ 2,566,690	$ (2,495,710)	$ 70,980	$ 2,566,690	$ (2,396,639)	$ 170,051

Licenses have a weighted average remaining amortization period of 7.5 months as of December 31, 2010. Amortization expense for intangible assets amounted to $68,247, $164,662 and $105,455 for the years ended December 31, 2010, 2009, and 2008, respectively. Additionally, during 2009, licenses that were used for the manufacture of certain of the Company s consumables were impaired due to the Company outsourcing this manufacturing process. This resulted in an impairment charge of $549,148 charged to cost of sales. In addition, an impairment of $91,105 was recorded as a general and administrative expense. Estimated future amortization expense for these licenses is as follows:

Years Ending December 31,	
2011	$ 61,749
2012	9,231
Total	$ 70,980

4. Share-based compensation

The Company recognizes share-based compensation expense related to share options, warrants and restricted stock issued to employees and directors in exchange for services. The compensation expense is based on the fair value of the awards, which are determined by utilizing various assumptions regarding the underlying attributes of the options and shares. The estimated fair value of options granted and restricted stock, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a straight line basis over the period the vesting occurs. The share-based compensation expense is recorded in cost of sales, sales and marketing, research and development and general and administrative expenses based on the employee s

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respective function. The option and warrant-related 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 life of the option or warrant, the expected volatility and other factors. The compensation expense related to the 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.

On June 3, 2010, the Company exchanged all of the outstanding options under the Osmetech plc 2003 U.S. Equity Compensation Plan (the U.S. Plan) for options under the 2010 Equity Incentive Plan (the Plan). The options were exchanged using an exchange ratio of 230 options to purchase shares of Osmetech plc to one share of the Company and 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 is at the discretion of the compensation committee or senior management of the Company. All options are exercisable at a price equal to the average closing quoted market price of the Company s shares on the NASDAQ on the date of grant and generally vest between 1 and 4 years.

Options are generally exercisable for a period up to 10 years after grant and are forfeited if the employee leaves the Company before the options vest. As of December 31, 2010, 687,965 shares remained available for future grant of awards under the Plan. Restricted stock grants reduce the amount of stock options available for grant under the 2010 Plan and are excluded from the table below.

The following table summarizes stock option activity during the year ended December 31, 2010:

	Number of shares	Weighted average exercise price (translated to dollars)
Outstanding at December 31, 2009	993,214	$ 6.96
Granted	429,300	5.29
Exercised	(21,589)	0.37
Cancelled	(293,005)	(5.48)
Outstanding at December 31, 2010	1,107,920	$ 6.40
Exercisable at December 31, 2010	437,399	$ 7.16

The weighted average fair value of options granted during 2010, 2009 and 2008 was $5.29, $3.68 and $27.37, respectively. The intrinsic value of options exercised in 2010, 2009 and 2008 was $136,157, $0 and $3,116, respectively. No options were exercised in 2009. As of December 31, 2010, there were 992,565 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.56 years, and an aggregate intrinsic value of $0. Options that are exercisable as of December 31, 2010 have a remaining weighted average contractual term of 7.52 years, and an aggregate intrinsic value of $0.

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, 2010, 2009 and 2008 with the following assumptions:

	Year Ended December 31,		
	2010	2009	2008
Expected volatility (%)	70.0	66.7	49.0
Expected life (years)	5.91	0.4	3.0
Risk free rate (%)	2.1	2.2	4.6
Expected dividend yield (%)	0	0	0

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Share Warrants During 2009, the Company issued warrants to purchase 132,475 of Osmetech s ordinary shares with an exercise price of £4.60 per share, and 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, the warrant to purchase 132,475 was cancelled upon the closing of the IPO. At the same time, the warrant to purchase 88,317 of Osmetech s ordinary shares was converted to 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 shall continue to be exercisable up to and including the earlier to occur of (i) 60 days after the director leaving the Company s board of directors (for whatever reason) and (ii) June 30, 2012.

Additionally, Osmetech s deferred shares, which were created at the time of a 10-for-1 consolidation of ordinary shares on September 30, 2005 are excluded from basic and diluted net loss per ordinary share. Management considers these shares to be of minimal value. The deferred shares do not entitle the holder to payment of any dividend or other distribution or to receive notice or attend or vote at any general meeting of Osmetech. The deferred shares are non transferable. In the event of a return of assets on winding up of Osmetech, the deferred shareholders receive 1 pence in respect of their shareholding in its entirety.

During the year ended December 31, 2010, the company granted 161,329 shares of restricted stock to two board members.

The restricted stock granted to the Interim Chief Executive Officer vests over the twelve month period ending July 2011 and the restricted stock granted to our new board member vests over the four year period of his board of director s duties and over the twelve month period ending August 2011, for his initial and annual board compensation grants, respectively.

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

	Year Ended December 31,		
	2010	**2009**	**2008**
Cost of sales	$ 18,916	$ 19,364	$ 23,243
Sales and marketing	260,823	37,344	44,826
Research and development	162,065	48,409	58,107
General and administrative	1,111,067	1,205,916	(382,395)
	$ 1,552,871	$ 1,311,033	$ (256,219)

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, 2010, 2009 and 2008. During 2008, the Company determined that certain performance based criteria for options previously issued to certain executives would not be met. Accordingly, all expenses that had previously been recognized were reversed. No other options with performance based conditions have been outstanding during the periods presented. At December 31, 2010, the estimated total remaining unamortized compensation expense, net of forfeitures, associated with share-based awards was $2,728,305 which is expected to be recognized over a weighted-average period of 1.42 years.

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5. Income Taxes

The components of loss before income taxes were as follows:

	Year Ended December 31,		
	2010	**2009**	**2008**
Domestic (U.S. Entities)	$ (18,387,668)	$ (18,332,641)	$ (25,585,488)
Foreign (Non U.S. Entities)	0	(1,768,738)	(2,530,409)
	$ (18,387,668)	$ (20,101,379)	$ (28,115,897)

The components of the income tax expense (benefit) for continuing operations are as follows for the years ended December 31:

	2010	**2009**	**2008**
Current expense (benefit):			
U.S. Provision	$	$ (165,339)	$
State	15,324	2,872	8,583
Foreign (Non-U.S. entities)			180,023
Total Current	15,324	(162,467)	188,606
Non-current expense			
U.S. Provision			
State		23,697	58,130
Foreign (Non-U.S. Entities)			
Total Non-current expense		23,697	58,130
Deferred expense			
U.S. Provision			
State			
Foreign (Non-U.S. Entities)			
Total Deferred Expense			
Total Expense	$ 15,324	$ (138,770)	$ 246,736

The components of net deferred income taxes consist of the following as of December 31:

	2010	**2009**	**2008**
Current deferred income tax assets (liabilities):			
Compensation Accruals	$ 676,350	$ 82,262	$ 95,135
Accruals and Reserves	304,704	568,189	837,665
State Tax Provision	10,587	1,251	8,099
Federal Benefit of State UTP	165,580		
Valuation allowance	(1,157,221)	(651,702)	(940,899)
Total current deferred income taxes			

Noncurrent deferred income tax assets (liabilities):			
Depreciation and Amortization	960,808	1,068,097	(98,712)
Intercompany Interest Expense	1,980,233	2,140,075	2,006,305
NOL and Credits	8,996,736	34,941,648	26,949,147
Valuation allowance	(11,937,777)	(38,149,820)	(28,856,740)
Total noncurrent deferred income taxes			
Net deferred income taxes	$	$	$

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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 as follows:

	2010	2009	2008
U.S. Federal statutory income tax rate	34.0%	34.0%	34.0%
Permanent Differences	0.4%	(0.1%)	(1.8%)
State Taxes	(0.1%)	(0.1%)	(0.2%)
Effect of non-U.S. Operations	(0.0%)	(0.5%)	(0.5%)
Effective Rate Change non- U.S.	(0.0%)	(0.7%)	(2.1%)
Valuation allowance	(34.4%)	(31.9%)	(30.3%)
Total tax provision	(0.1%)	0.7%	(0.9%)

As of December 31 2010, the Company had net operating loss carryforwards of approximately $77.9 million and $72.6 million for federal and state income tax purposes, respectively. These may be used to offset future taxable income and will begin to expire in varying amounts through 2030. In addition, the Company has non-U.S. net operating loss carryforwards of $30.4 million. Because the Company intends to restructure 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.

Internal Revenue Code Section 382 places a limitation on future utilization of the federal and state net operating losses, to the extent that the Company incurs an ownership change as defined by Section 382. The Company has determined that it has experienced multiple ownership changes under Section 382. Management has estimated that approximately $24.7 million and $9.5 million of federal and state net operating losses, respectively, can be utilized in the future based on limitations that it has calculated under Section 382. As of December 31, 2010 approximately $10 million of federal net operating losses are available immediately. Additionally, federal net operating losses ranging from $0.2 million to $2.3 million become available each year. Management is currently analyzing alternative positions and additional factual information that may increase the amount of net operating losses that could subsequently be utilized up to $41.6 million and $24.7 million of federal and state net operating losses, respectively. To the extent that this additional information becomes available and could increase net operating losses available for use, the Company would adjust its deferred tax assets accordingly, with a corresponding adjustment to its valuation allowance. Utilization of net operating losses is also dependent upon sufficient taxable income generated within the appropriate carryforward periods.

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, 2010. 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, 2010, a valuation allowance of $13.1 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 estimates of future taxable income during the carryforward period are reduced or 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 our projections for growth.

The Company adopted certain 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

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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. In accordance with the adoption, a reconciliation of the beginning and ending amount of unrecognized tax benefits, exclusive of accrued interest and penalties, is as follows:

	2010	2009	2008
Balance at January 1	$ 382,000	$ 382,000	$ 382,000
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	$ 382,000	$ 382,000	$ 382,000

At December 31, 2010 and 2009, the Company classified $486,770 and $463,000, respectively, of total unrecognized tax benefits, which includes accrued interest and penalties of $104,770 and $81,000 for 2010 and 2009, 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 UK, US and various states jurisdictions. As of December 31, 2010 the Company s tax years after 2007 are subject to examination by the UK tax authorities. Except for net operating losses generated in prior years carrying forward to the current year, as of December 31, 2010, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2006.

6. Commitments and Contingencies

The Company has various operating lease agreements for its office, manufacturing, warehousing and laboratory space. Rent and operating expenses charged were $958,607, $1,124,655 and $1,228,173 for the years ended December 31, 2010, 2009, and 2008, respectively. Pursuant to the Company s lease agreements, a portion of the monthly rental has been deferred. The balance deferred as at December 31, 2010 and 2009 was $133,542 and $186,949, respectively.

Annual future minimum obligations for operating leases as of December 31, 2010 are as follows:

Years Ending December 31,	Operating leases
2011	$ 992,471
2012	565,362
2013	582,155
2014	598,947
2015	617,606
Thereafter	1,346,543
Total minimum lease payments	$ 4,703,084

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7. Inventory

Inventory on hand as of December 31, 2010 and 2009 was comprised of the following:

	2010	2009
Raw materials	$ 396,956	$ 38,973
Work-in-process	103,013	31,062
Finished goods	396,840	66,932
	$ 896,809	$ 136,967

The increase in raw materials and finished goods inventory is due to incremental revenue growth and inventory build-up in anticipation of the move of the manufacturing facility from Pasadena, California, to Carlsbad, California.

8. Property and Equipment, net

Property and equipment was comprised of the following as of December 31, 2010 and 2009:

	2010	2009
Property and equipment at cost:		
Plant and machinery	$ 2,451,775	$ 2,201,033
Rental systems	2,821,665	2,073,082
Office equipment	1,541,544	1,079,214
Leasehold improvements	597,523	74,394
Total property and equipment at cost	7,412,506	5,427,723
Less accumulated depreciation	(4,710,029)	(4,046,105)
Net property and equipment	$ 2,702,478	$ 1,381,618

The depreciation expense amounted to $995,064, $1,404,412 and $1,052,200 for the years ended December 31, 2010, 2009 and 2008 respectively.

During 2010, $288,962 of deposits on systems were transferred from other current assets to property and equipment, net. During 2009, $256,909 of systems were transferred out of finished goods inventory into property and equipment, net. These transfers were as a result of a change in the Company s strategy from outright sales of systems to placing systems with customers for no initial charge and recovering that cost through the sale of test cartridges pursuant to reagent rental agreements.

In 2009, due to the anticipated acceleration of the release of future generations of the Company s products, in particular the NexGen system, the Company assessed all systems for impairment. For systems placed with customers the carrying amount was written down to fair value based on the projected discounted net cash flows to be generated from the sale of test cartridges. Systems that were not expected to generate any future revenues were impaired to $0. The Company recorded an aggregate impairment charge of $865,389 of which $665,718 was charged to cost of sales in respect of systems placed with customers, $69,959 was charged to research and development expenses in respect of systems being used for research purposes, and $129,712 was charged to sales and marketing expenses in respect of systems being used for demonstration purposes only. Additionally in 2009, the Company revised the estimated useful life of systems from 5 to 3 years, although this did not result in a material increase in the depreciation charge during the year.

9. Employee Benefit Plan

The Company has a 401(k) tax-deferred savings plan, whereby eligible employees may contribute a percentage of their eligible compensation. Company contributions are discretionary. Including administrative fees, the

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expense was $78,572, $172,668 and $304,449 for the years ended December 31, 2010, 2009 and 2008, respectively. Additionally, the Company has made contributions to other defined contribution plans on behalf of its employees amounting to $0, $58,004 and $98,325 for the years ended December 31, 2010, 2009 and 2008, respectively. These other defined contribution plans were terminated in 2010.

10. Fair Value of Financial Instruments

The Company s financial instruments consist of cash equivalents, accounts receivable, and accounts payable. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments.

Accounting literature provides a fair value hierarchy, which classifies fair value measurements based on the inputs used in measuring fair value. These inputs include: Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Cash and cash equivalents: The carrying amounts reported in the balance sheets for cash and cash equivalents are stated at their fair market value. Cash and cash equivalents are classified as Level 1.

Foreign exchange contracts: The Company does not use derivative financial instruments for speculative or trading purposes. Prior to 2009, the Company entered into foreign exchange forward contracts to hedge certain balance sheet exposures and intercompany balances against movement in foreign exchange rates. Gains and losses on the foreign exchange contracts were included in interest and other income, net, which offset foreign exchange gains or losses from revaluation of foreign currency-denominated balance sheet items and intercompany balances.

The foreign exchange forward contracts required the Company to exchange foreign currencies to U.S. dollars or vice versa, and generally mature in one month or less. As of December 31, 2010, 2009 and 2008, the Company had outstanding foreign exchange forward contracts with aggregate notional amounts of $0, $0 and $6.0 million, respectively, which had remaining maturities of less than six months. The fair value recorded on the consolidated balance sheets for foreign exchange contracts is not material.

Non-recurring measurements: The Company measures the fair value of its long-lived assets on a periodic basis when it appears that there may be requirement to do so, such as an indication of impairment. During the year ended December 31, 2009, impairment indicators required that an assessment of the fair value of certain intangible assets and systems. These fair value measurements were done on the basis of unobservable Level 3 inputs, for which little or no market data exists. These inputs included the assumptions of future cash flows related to the items, and a discount rate applied to these cash flows. The assumed cash flows were projected based on management s best estimates for the remaining net cash flows for each item over its the estimated remaining useful life. Due to the relatively short-term period of future cash flows on these items, the use of a discount rate did not have a material impact on the valuation of these items. Impairments recorded during the period as a result of these fair value measurements were $640,253 for intangible assets (note 3), and $865,389 on the laboratory systems (note 8).

There were no transfers of items between Levels 1, 2 or 3.

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11. Other current assets and liabilities, and other non-current liabilities consisted of the following as of December 31, 2010 and 2009:

	2010	2009
Other current assets		
Therapeutic discovery credit receivable	$ 1,645,292	$
Deposits and prepaid expenses	290,920	344,558
Tax receivable	256,948	
Other		647,623
Total	$ 2,193,160	$ 992,181
Other non-current assets		
Deposit	$ 55,355	$
Total	$ 55,355	$
Other current liabilities		
Accrued professional fees	$ 350,097	$ 544,524
Rental related liabilities	330,424	188,070
Accrued warranties	179,594	
Other	389,813	153,438
Total	$ 1,249,928	$ 886,032
Other non-current liabilities		
Liability pertaining to uncertain tax position	$ 486,770	$ 463,000
Tax payable	10,516	
Rental related liabilities	115,646	332,334
Total	$ 612,932	$ 795,334

In July 2010, the Company applied for certification of qualified investments eligible for credits and grants under the qualifying therapeutic discovery project program for the years ending December 31, 2009 and December 31, 2010. The $1.6 million in grant applications were for $561,000 of expenditures in 2009 and $1.1 million of expenditures in 2010.

These development projects included the NexGen System (formerly the AD-8 system), K-ras mutation cancer treatment, Plavix Sensitivity Drug, Warfarin Sensitivity Test, Thrombophilia Risk Test, Respiratory Viral Panel and Cystic Fibrosis Genotyping. In November 2010, the company was notified that it had been awarded a total of $1.6 million under the program. As of December 31, 2010, the Company recorded the $1.6 million tax credit as an Other Current Assets on the Balance Sheet with a corresponding credit to Other Income on the Consolidated Statement of Operations.

In February 2011, the Company requested payment from the U.S. Department of Treasury, and $1.6 million in cash was received.

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12. Selected Quarterly Financial Data (Unaudited)

	2010 Quarters (in thousands, except per share data)			
	First	Second	Third	Fourth
Total revenue	$ 399	$ 651	$ 667	$ 787
Gross loss	$ (168)	$ (212)	$ (554)	$ (939)
Loss from operations	$ (4,847)	$ (5,142)	$ (4,924)	$ (5,118)
Net loss	$ (4,849)	$ (5,137)	$ (4,917)	$ (3,500)
Per share data:				
Net loss per common share basic and diluted	$ (0.68)	$ (0.60)	$ (0.42)	$ (0.30)

	2009 Quarters (in thousands, except per share data)			
	First	Second	Third	Fourth
Total revenue	$ 188	$ 249	$ 255	$ 306
Gross loss	$ (1,186)	$ (484)	$ (506)	$ (1,158)
Loss from operations	$ (4,628)	$ (4,264)	$ (5,648)	$ (5,898)
Net loss	$ (4,144)	$ (4,267)	$ (5,653)	$ (5,628)
Per share data:				
Net loss per common share basic and diluted	$ (1.14)	$ (1.08)	$ (1.13)	$ (1.07)

13. Subsequent Events

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 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of December 31, 2010) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. As of December 31, 2010, the Company had not drawn any funds under this loan and security agreement.

In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased by $1 million to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

An additional loan was made available under the amended loan and security agreement for up to $1 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of March 11, 2011, the Company had no outstanding loans on the line of credit and had drawn $2 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original term loan. The loan bears an interest rate of 7.5%.

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Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, including our Interim Chief Executive Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Interim Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, and not absolute, assurance of achieving the desired objectives. In reaching a reasonable level of assurance, management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Interim Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2010 at the reasonable assurance level.

Exemption from Management s Report on Internal Control Over Financial Reporting for the Fiscal Year Ended December 31, 2010

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarterly period ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. In the fourth quarter of 2010, the Company enhanced its financial close and reporting procedures.

ITEM 9B. OTHER INFORMATION

On March 9, 2011, we entered into an amendment to our loan and security agreement with Square 1 Bank (the Loan Agreement), pursuant to which we amended the terms of our initial available equipment loan (the Initial

Equipment Loan). Under the new terms of the Initial Equipment Loan, we may request advances for the purchase of equipment and software approved by Square 1 Bank at any time though July 12, 2011 in an amount not to exceed $2 million subject to certain restrictions.

Pursuant to the amendment, we also agreed to terms on a second available equipment loan (the Second Equipment Loan). Under the terms of the Second Equipment Loan, we may request advances for the purchase of equipment and software approved by Square 1 Bank at any time through March 9, 2012 in an amount not to exceed $1 million subject to certain restrictions.

Interest on any advances under the Initial Equipment Loan and the Second Equipment Loan will accrue at a variable annual rate equal to the greater of (i) the bank s prime rate plus 3.25%, or (ii) 6.50%, unless we are not in compliance with certain of our financial covenants under the Loan Agreement, in which case interest shall accrue at the greater of (i) the bank s prime rate plus 4.25%, or (ii) 7.50%. Interest on the Initial Equipment Loan is payable at the beginning of each month prior to July 12, 2011, after which principal and interest is payable in 24 equal monthly installments beginning on August 12, 2011 through the maturity date. Interest on the Second

Equipment Loan is payable at the beginning of each month prior to March 9, 2012, after which principal and interest is payable in 24 equal monthly installments beginning on April 9, 2012 through the maturity date.

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PART III.

Certain information required by Part III is omitted from this report because the Company will file a definitive proxy statement within 120 days after the end of its fiscal year pursuant to Regulation 14A (the Proxy Statement) for its annual meeting of stockholders to be held on May 25, 2011, and certain information included in the Proxy Statement is incorporated herein by reference.

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

(a) The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

(b) Identification of Executive Officers. Information concerning our executive officers is set forth under Executive Officers in Part I of this Annual Report on Form 10-K and is incorporated herein by reference.

(c) The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

(d) The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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. The information on, or that can be accessed from, our website is not incorporated by reference into this report.

Item 11. EXECUTIVE COMPENSATION

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

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

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULE

1. Financial Statements: See Index to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

2. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

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SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 11, 2011.

GENMARK DIAGNOSTICS, INC.

By: /s/ CHRISTOPHER GLEESON
Name: Christopher Gleeson
Title: Chairman and Interim Chief Executive Officer (principal executive officer and principal financial officer)

March 11, 2011

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher Gleeson, his or her 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 or her 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 and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHRISTOPHER GLEESON **Christopher Gleeson**	Chairman of the Board and President and Interim Chief Executive Officer (principal executive officer and principal financial officer)	March 11, 2011
/s/ DARYL J. FAULKNER **Daryl J. Faulkner**	Director	March 11, 2011
/s/ JAMES FOX **James Fox**	Director	March 11, 2011
/s/ JON FAIZ KAYYEM **Jon Faiz Kayyem**	Chief Scientific Officer and Director	March 11, 2011
/s/ KEVIN C O BOYLE **Kevin C O Boyle**	Director	March 11, 2011

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INDEX TO EXHIBITS

Exhibit Number	Description of Exhibits
1.1	Form of Underwriting Agreement. (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 13, 2010).
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	By-Laws (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	Commercial Lease Agreement between Collis P. and Howard Huntington Memorial Hospital Trust and Osmetech Technology Inc., dated March 24, 2008 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
10.3	First Amendment to Commercial Lease Agreement between Collis P. and Howard Huntington Memorial Hospital Trust and Osmetech Technology Inc., dated February 1, 2009 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).
10.4	Second Amendment and Termination of Commercial Lease Agreement between Collis P. and Howard Huntington Memorial Hospital Trust and Osmetech Technology Inc., dated November 1, 2009 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).
10.5	Commercial Lease Agreement between Kandamerica, Inc., and Osmetech Inc., dated August 1, 2005 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).
10.6	Amendment to Commercial Lease Agreement between Kandamerica, Inc., and Osmetech Inc., dated March 12, 2008 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).
10.7	License Agreement by and between California Institute of Technology and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated February 8, 1995 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 21, 2010). ++
10.8	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). ++
10.9	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). ++

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Exhibit Number	Description of Exhibits
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).++
10.12	Non-Exclusive License Agreement by and between The Johns Hopkins University and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, dated December 29, 2006 (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on May 25, 2010).++
10.13	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).++
10.14	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).++
10.15	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). +
10.16	Form of Stock Option Agreement (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).+
10.17	Form of 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).+
10.18	Executive Employment Agreement, dated January 1, 2010, by and between Osmetech Technology Inc. and Jon Faiz Kayyem (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+
10.19	Executive Employment Agreement, dated November 30, 2009, by and between Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics and Steven Kemper (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+
10.20	Executive Employment Agreement, dated January 1, 2010, by and between Osmetech Technology Inc., and Pankaj Singhal (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+
10.21	Executive Employment Agreement, dated March 1, 2010, by and between Osmetech Technology Inc. and John Bellano (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+
10.22	Compromise Agreement, dated August 10, 2009, by and between Osmetech plc and James White (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+

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Exhibit Number	Description of Exhibits
10.23	Compromise Agreement, dated March 10, 2010, by and between Osmetech plc and David Sandilands (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).+
10.24	Loan and Security Agreement, dated March 12, 2010, by and among Square 1 Bank and Osmetech Technology Inc., Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, and GenMark Diagnostics, Inc. (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	First Amendment to Loan and Security Agreement, dated August 17, 2010, by and among Square 1 Bank and Osmetech Technology, Inc., Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, and GenMark Diagnostics, Inc.
10.26	Second Amendment to Loan and Security Agreement, dated August 17, 2010, by and among Square 1 Bank and Osmetech Technology, Inc., Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, and GenMark Diagnostics, Inc.
10.27	Third Amendment to Loan and Security Agreement, dated August 17, 2010, by and among Square 1 Bank and Osmetech Technology, Inc., Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics, and GenMark Diagnostics, Inc.
10.28	Manufacturing Services Agreement, dated February 1, 2007, by and between Aubrey Group, Inc. and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).++
10.29	First Amendment to Manufacturing Services Agreement, dated May 7, 2009, by and between Aubrey Group, Inc. and Clinical Micro Sensors, Inc. dba Osmetech Molecular Diagnostics (incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on April 20, 2010).
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).
23.2	Consent of Deloitte LLP (UK).
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of the principal executive officer and 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

\+ Management Compensation Plan
++ Confidential Treatment Granted