

GenMark Diagnostics, Inc.
Form 424B4
June 01, 2010
Table of Contents

Filed Pursuant to Rule 424(b)(4)

Registration No. 333-165562

4,600,000 Shares

GENMARK DIAGNOSTICS, INC.

Common Stock

\$6.00 per share

GenMark Diagnostics, Inc. is offering 4,600,000 shares.

Trading symbol: NASDAQ Global Market GNMK

This is the initial public offering of shares of GenMark Diagnostics, Inc. and no public market currently exists for these shares.

This investment involves risk. See **Risk Factors** beginning on page 9.

	Per Share	Total
Public offering price	\$6.00	27,600,000
Underwriting discount	\$0.42	1,932,000
Proceeds, before expenses, to GenMark Diagnostics, Inc.	\$5.58	25,668,000

The underwriters have a 30-day option to purchase up to 690,000 additional shares of common stock from us to cover over-allotments, if any.

*At our request, the underwriters have reserved shares with an aggregate public offering price of up to \$10,150,000 for purchase by our directors and employees. See *Underwriting* beginning on page 113.*

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

William Blair & Company

Piper Jaffray

ThinkEquity LLC

The date of this prospectus is June 1, 2010

Table of Contents

Table of Contents

TABLE OF CONTENTS

	Page
<u>Prospectus Summary</u>	1
<u>Risk Factors</u>	9
<u>Special Note Regarding Forward Looking Statements</u>	30
<u>Reorganization of Osmetech plc</u>	31
<u>Use of Proceeds</u>	32
<u>Dividend Policy</u>	33
<u>Capitalization</u>	34
<u>Dilution</u>	36
<u>Selected Consolidated Financial Data</u>	38
<u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	41
<u>Business</u>	54
<u>Management</u>	79
<u>Executive Compensation</u>	84
<u>Principal Stockholders</u>	98
<u>Related Party Transactions</u>	100
<u>Description of Capital Stock</u>	102
<u>Shares Eligible For Future Sales</u>	106
<u>Certain Material U.S. Federal Income and Estate Tax Considerations to Non-U.S. Holders</u>	109
<u>Underwriting</u>	113
<u>Legal Matters</u>	117
<u>Experts</u>	117
<u>Where You Can Find More Information About Us.</u>	117
<u>Financial Statements</u>	F-1

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell, nor are we or the underwriters seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside of the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come

Table of Contents

into possession of this prospectus in any jurisdiction outside of the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

This prospectus contains market data and industry forecasts that were obtained from industry publications, third-party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable, but we have not independently verified the accuracy and completeness of such information. The Company has paid for market research information provided by L.E.K. and Kalorama which appears in this prospectus.

Some numerical figures included in this prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in certain tables may not be an arithmetic aggregation of the figures that preceded them.

eSensor[®], Osmetech[®], GenMarkDx and our logo are our trademarks. This prospectus also includes trademarks, trade names and service marks that are the property of other organizations.

Table of Contents

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. Therefore, you should also read the more detailed information set out in this prospectus and the financial statements included elsewhere in this prospectus.

*In this prospectus, unless the context otherwise requires, the terms *we*, *us*, and *our*, refer both to GenMark Diagnostics, Inc. and Osmetech plc on a consolidated basis giving effect to the reorganization discussed below. In addition, *GenMark* refers to GenMark Diagnostics, Inc., and *Osmetech* refers to Osmetech plc.*

Immediately prior to the closing of this offering, Osmetech, a corporation registered in England and Wales, will become a subsidiary controlled by GenMark, a Delaware corporation. Under English law, it is not possible to change the place of incorporation of Osmetech from one jurisdiction to another, so it was necessary to establish GenMark as the new parent company of Osmetech. GenMark was incorporated solely for this purpose and has nominal assets and no operations.

The establishment of GenMark as the new parent company of Osmetech will be achieved through a scheme of arrangement under Part 26 of the U.K. Companies Act of 2006. Pursuant to the scheme of arrangement, if approved, the shareholders of Osmetech agree that their ordinary shares in Osmetech will be cancelled in consideration for (i) the issuance to Osmetech shareholders of shares of common stock in GenMark and (ii) the issuance by Osmetech of new shares to GenMark.

Our Company

We are a molecular diagnostics company, or a company which detects and measures DNA and RNA targets to diagnose disease and to optimize the treatment of patients, focused on developing and commercializing our eSensor detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct segments of target DNA, which we refer to as biomarkers, in a single sample. We received 510(k) clearance for our XT-8 System from the Food and Drug Administration, or FDA. Our XT-8 System 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 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, Warfarin Sensitivity Test and Thrombophilia Risk Test have received FDA clearance. Our Respiratory Viral Panel Test is currently labeled for investigational use only, or IUO, and we intend to obtain FDA clearance for this test. We also have a pipeline of eight potential products in development or design, including a Plavix Sensitivity Test and a K-ras Mutation Test, which are described below.

We are designing our next-generation AD-8 System to integrate DNA amplification with our eSensor detection technology to enable technicians to place a minimally prepared patient sample into our cartridge and obtain results without any additional steps. We believe this sample-to-answer

Table of Contents

capability will 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 enable our customers to perform a broad range of diagnostic tests, in some cases providing sources of diagnostic test revenue previously unavailable to them. We believe our technology will also improve patient care 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. In addition, we believe these tests will be economically attractive to our customers because the tests reduce technicians' time and labor in comparison to competing diagnostic tests and are generally covered by third-party payors through established reimbursement codes. By providing an attractive value proposition to health care providers and patients, we intend to drive widespread adoption of our technology.

Through March 31, 2010, our revenues were principally derived from product sales of our Cystic Fibrosis Genotyping Test and, to a lesser extent, sales of our Warfarin Sensitivity Test. We also received revenues from the out-licensing of our electrochemical detection technology and the sale of two XT-8 instruments.

Recent Developments

Beginning in the summer of 2009, we initiated a number of actions focused on improving our business and implementing our new strategy, including:

Appointed our New Chief Executive Officer. In August 2009, we retained Jon Faiz Kayyem, Ph.D. as our Chief Executive Officer. Dr. Kayyem is an inventor of our core electrochemical detection technology and led our predecessor company, Clinical Micro Sensors, through its acquisition by Motorola, Inc. in 2000 for approximately \$280 million.

Strengthened our Management and Board of Directors. Steven Kemper joined as our Chief Financial Officer, and Christopher Gleeson and Kevin C. O'Boyle joined as independent directors. Each of these individuals has significant experience in growing early stage medical technology companies into high growth health care enterprises.

Established a New Commercial Organization. In late 2009, we added senior executives to our commercial operations and marketing groups and expanded our direct sales force. We are now focusing our sales efforts on the top 1,000 potential users of our XT-8 System in the United States, primarily high volume national and regional reference laboratories and hospitals.

Adopted a New Product Development Strategy. In addition to our current test menu, we are developing or designing eight additional tests for our XT-8 System. We are also developing our next-generation sample-to-answer diagnostic system, the AD-8 System.

Streamlined Operations. We closed multiple facilities in the United States and United Kingdom. We further intend to close our two facilities in Pasadena, California and consolidate operations into a single facility in Carlsbad, California in the fourth quarter of 2010.

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

Table of Contents

especially those reference laboratories and hospitals in the United States that perform a high volume of molecular diagnostic tests. To achieve this objective, we intend to:

expand our menu of clinical diagnostic products;

grow our installed base of customers;

increase utilization of our tests;

develop our next-generation AD-8 System; and

expand internationally and explore out-licensing opportunities.

Market Opportunity and Limitations of Current Technologies

The U.S. market for molecular diagnostics was estimated to be \$1.9 billion in 2009 and is anticipated to reach \$3.4 billion in 2014 according to L.E.K., a market research firm. Many factors are driving growth of this market, including the expansion of genetic testing for disease predisposition, advances in personalized medicine, such as the tailoring of cancer therapies to those individuals most likely to respond, and increased demand for infectious disease diagnostics panels.

Commercially available molecular diagnostic testing systems, as well as home-brew or laboratory developed tests, or LDTs, are characterized by the following limitations:

Limited Menu of Diagnostic Tests. LDTs are typically custom designed for one specific genetic biomarker or disease. In addition, testing systems marketed as alternatives to LDTs currently offer only a limited number of tests for use with such systems.

Inability to Multiplex. Testing systems often lack the capacity to multiplex, or test for multiple biomarkers at the same time on a single patient sample. As a result, the laboratory must perform multiple, separate tests.

Poor Laboratory Workflow. Many LDTs and testing systems require significant sample preparation and washing steps, frequent calibration and time-consuming maintenance.

Risk of Human Error. Many LDTs and testing systems require technicians to perform complex manual procedures, which may lead to contamination. In addition, LDTs and many testing systems require the operator to interpret results, which increases the potential for human error.

Intensive Resource Requirements. Laboratories need highly skilled technicians and dedicate significant capital, labor and laboratory space to conduct molecular diagnostic tests. Many multiplex tests currently used by national reference laboratories are so specialized that we believe only a limited number of their sites can perform these tests.

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

Shifting Regulatory Environment. Many LDTs and testing systems have not been submitted for FDA clearance. The FDA has imposed regulatory requirements on laboratories that use these tests. In the future, the FDA may further restrict use of non-FDA-cleared tests.

Our Solution

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 consists of a compact bench-top workstation and self-contained, disposable test cartridges. We

Table of Contents

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. We have three FDA-cleared tests and one test labeled for IUO. We also have a pipeline of eight additional products in development or design. We intend to introduce two to four new tests annually.

FDA-Cleared Products. We have received FDA clearance for our Cystic Fibrosis Genotyping Test, Warfarin Sensitivity Test and Thrombophilia Risk Test. We intend to submit our Respiratory Viral Panel Test to the FDA for clearance in 2011.

Ease of Use. Our XT-8 System minimizes manual processing steps and streamlines data analysis, making molecular diagnostic testing available to a broad spectrum of laboratories. Our system requires minimal maintenance.

Accuracy and Reliability. Our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test demonstrated 100% accuracy in clinical studies compared to DNA sequencing. Our XT-8 System limits technician contact with a patient sample, reducing contamination risk, and provides clear reports, minimizing the risk of human error.

Enhanced Laboratory Work Flow. Our technology streamlines the sample preparation process and can produce results within 30 minutes of receipt of the amplified DNA sample. Our XT-8 System provides random access, or the ability to initiate tests while other tests are in progress, for up to 24 independent test cartridges.

Multiplex Capability. Our XT-8 System currently enables testing each sample for 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.

Our Diagnostic Tests

We currently offer four diagnostic tests for use with our XT-8 System, three of which have received 510(k) clearance from the FDA and one of which is currently labeled for IUO. We also have eight additional diagnostic tests in the development or design stage.

Test	Intended Application
FDA-Cleared Tests	
Cystic Fibrosis Genotyping	Detects the most common mutations associated with cystic fibrosis
Warfarin Sensitivity	Identifies biomarkers associated with an individual's ability to metabolize the oral anti-coagulant warfarin
Thrombophilia Risk	Detects the most common mutations associated with increased risk of blood clots
IUO Test	
Respiratory Viral Panel	Detects major respiratory viruses and aids in the identification of respiratory infections

Table of Contents

Test	Intended Application
Tests in Development or Design	
Plavix Sensitivity	Identifies biomarkers associated with the metabolism of Plavix, a commonly prescribed anti-coagulant
K-ras Mutation	Detects mutations in the K-ras gene associated with response to anti-epidermal growth factor receptor therapy, or anti-EGFR therapy, a type of cancer treatment that interferes with the growth of cancer cells
Lower Respiratory Tract Infections	Detects major viral and bacterial causes of lower respiratory tract infections
Central Nervous System Infections	Detects major infectious agents associated with meningitis and encephalitis
Hepatitis C Virus Genotyping	Identifies type and subtype of the hepatitis C virus
2D6 Tamoxifen Metabolism	Identifies patients with altered 2D6 metabolism that can affect the effectiveness of tamoxifen, a drug used for the prevention and treatment of breast cancer
EGFR Pathway	Detects mutations in other genes besides K-ras involved in EGFR signaling
Human Papillomavirus Genotyping <i>Our AD-8 System</i>	Identifies human papillomavirus types associated with cervical cancer

We are developing our next-generation testing system, the AD-8 System, to integrate DNA amplification with eSensor DNA detection. We are designing the AD-8 System to provide the same customer benefits of the XT-8 System and to further enhance workflow by reducing the level of sample processing required and incorporating DNA amplification. We believe this advancement will make our technology attractive to the broad range of institutions that currently lack the technical or economic resources to perform molecular diagnostic testing. As a result, we believe the AD-8 System may expand our target user base from 1,000 to over 5,000 laboratories and hospitals in the United States. The AD-8 System is currently in development with technical feasibility completed using diluted blood in our Warfarin Sensitivity Test.

Selected Risk Factors

Investing in our common stock involves substantial risk. Before participating in this offering, you should carefully consider all of the information in this prospectus, including risks discussed in Risk Factors beginning on page 9. Some of our most significant risks are:

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

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

We may fail to successfully expand the menu of diagnostic tests for our XT-8 System, obtain licenses to additional biomarkers on commercially reasonable terms or effectively predict the types of tests our existing customers want.

Table of Contents

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 sales depend on third-party payors reimbursing our customers for the use of our products at levels sufficient to for us to sell our products profitably.

We may not be successful in developing our next-generation AD-8 System.

Reorganization

GenMark was formed by Osmetech as a Delaware corporation in February 2010 and prior to this offering had nominal assets and no operations. Immediately prior to the closing of this offering, GenMark will acquire all of the outstanding ordinary shares of Osmetech in the Reorganization under the applicable laws of the United Kingdom, pursuant to which all of the issued ordinary shares in Osmetech will be 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. The Reorganization provides that Osmetech shareholders will receive one share of GenMark common stock for 230 ordinary shares of Osmetech, subject to any Osmetech shareholder who is due to receive fractional shares of GenMark common stock in the Reorganization will be entitled to receive a single share of GenMark in lieu of such fractional shares. Following the Reorganization, GenMark will hold all of the voting power of Osmetech and the former shareholders of Osmetech will hold shares of GenMark.

Office Location

The address of our principal place of business is 757 S. Raymond Avenue, Pasadena, CA 91105. Our office phone number is (626) 463-2000.

Table of Contents

The Offering

Issuer	GenMark Diagnostics, Inc.
Common stock we are offering	4,600,000 shares of common stock
Common stock outstanding after the offering	11,723,512 shares of common stock
Offering price	The initial public offering price is \$6.00 per share of common stock
Use of proceeds	We intend to use the net proceeds from this offering to develop a broad menu of tests, to fund our planned sales and marketing initiatives, to develop our AD-8 System and for general corporate purposes. See Use of Proceeds.

NASDAQ Global Market Symbol GNMK

The number of shares of our common stock outstanding immediately after this offering is based on 7,123,512 shares outstanding as of March 31, 2010 and excludes:

963,514 shares of common stock issuable upon exercise of options outstanding as of March 31, 2010, at a weighted average exercise price of \$7.45 per common share;

220,792 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2010, at a weighted average exercise price of \$8.32 per common share; and

2,000,000 shares of common stock which will be available for future grant or issuance under our 2010 Equity Incentive Plan, or our 2010 Plan, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2011.

Unless the context otherwise requires, all share and per share amounts in this prospectus have been adjusted on a pro forma basis to give effect to the Reorganization and assume that Osmetech shareholders will receive one share of GenMark common stock for 230 ordinary shares of Osmetech in the Reorganization, subject to any Osmetech shareholder who is due to receive fractional shares of GenMark common stock in the Reorganization becoming entitled to receive a single share of GenMark common stock in lieu of such fractional shares.

Unless otherwise indicated, all information in this prospectus assumes:

that the underwriters do not exercise their option to purchase up to 690,000 additional shares of our common stock to cover over-allotments, if any; and

no options, warrants or shares of common stock were issued after March 31, 2010, and no outstanding options or warrants were exercised after March 31, 2010.

Unless otherwise indicated, the exercise prices of the outstanding options and warrants are based upon the currency exchange rates of the U.S. dollar and British pound on March 31, 2010.

Table of Contents**SUMMARY CONSOLIDATED HISTORICAL FINANCIAL DATA**

The following summary consolidated historical financial information relates to Osmetech and its consolidated subsidiaries, which upon effectiveness of the Reorganization and prior to consummation of this offering, directly or indirectly, will be subsidiaries controlled by GenMark. Prior to the Reorganization, GenMark had nominal assets and no operations. The summary consolidated historical financial information of Osmetech and its consolidated subsidiaries for the years ended December 31, 2009, 2008 and 2007 and as of December 31, 2009 and 2008 has been derived from the audited consolidated financial statements of Osmetech appearing elsewhere in this prospectus and has been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The financial information as of March 31, 2010, and for the three months ended March 31, 2010 and March 31, 2009, is derived from Osmetech's unaudited condensed consolidated financial statements appearing elsewhere in this prospectus, and have been prepared in accordance with U.S. GAAP. Results for the three-month period ended March 31, 2010 are not necessarily indicative of the results of operations that may be expected for our full year performance. The summary consolidated historical financial data of Osmetech should be read together with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and unaudited condensed consolidated financial statements of Osmetech and related notes included elsewhere in this prospectus.

	Three months ended March 31,		Year Ended December 31,		
	2010	2009	2009	2008	2007
Consolidated Statements of Operations Data:					
Revenue:					
Product sales	\$ 384,249	\$ 177,911	\$ 910,527	\$ 559,592	\$ 234,099
License revenue	15,015	10,389	87,889	87,500	107,500
Total revenue	399,264	188,300	998,416	647,092	341,599
Cost of sales	567,396	1,374,561	4,332,299	3,237,869	2,624,589
Gross loss	(168,132)	(1,186,261)	(3,333,883)	(2,590,777)	(2,282,990)
Operating expenses:					
Sales and marketing	1,058,285	553,953	3,181,762	3,393,665	2,220,098
Research and development	1,453,759	1,430,348	5,633,717	13,423,679	12,554,236
General and administrative	2,167,264	1,457,434	8,288,762	9,632,708	8,895,796
Total operating expenses	4,679,308	3,441,735	17,104,241	26,450,052	23,670,130
Loss from operations	(4,847,440)	(4,627,996)	(20,438,124)	(29,040,829)	(25,953,120)
Other income:					
Foreign exchange (loss) gain	(1,110)	131,766	303,523	504,921	
Interest income	4,654	22,697	33,222	420,011	1,715,211
Total other income	3,544	154,463	336,745	924,932	1,715,211
Loss before income taxes					
	(4,843,896)	(4,473,533)	(20,101,379)	(28,115,897)	(24,237,909)
Benefit (provision) for income taxes	(5,049)	59,089	138,770	(246,736)	300,214
Net loss from continuing operations	\$ (4,848,945)	\$ (4,414,444)	\$ (19,962,609)	\$ (28,362,633)	\$ (23,937,695)
Net income (loss)	\$ (4,848,945)	\$ (4,414,444)	\$ (19,962,609)	\$ (28,362,633)	\$ 10,544,798
Unaudited pro forma net loss from continuing operations per common share, basic and diluted ⁽¹⁾					
	\$ (0.68)	\$ (1.14)	\$ (4.41)	\$ (28.13)	\$ (27.13)
Weighted average shares used in unaudited pro forma per share amounts ⁽¹⁾					
	7,113,922	3,876,553	4,526,758	1,008,386	882,325

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

(1) Based on a 1:230 exchange ratio in the Reorganization.

	As of March 31, 2010	As of December 31, 2009 2008	
Balance Sheet Data:			
Cash and cash equivalents	\$ 11,321,012	\$ 16,482,818	\$ 8,822,458
Total assets	16,129,662	19,333,477	15,175,215
Long-term liabilities	802,834	795,334	769,237
Total liabilities	5,336,172	4,008,659	5,237,946
Accumulated deficit	(130,938,834)	(126,089,889)	(106,127,280)
Total stockholders' equity	10,793,490	15,324,818	9,937,269

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the other information set forth in this prospectus, including our consolidated financial statements and the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, before deciding to invest in our common stock. If any of the events or developments described below occurs, our business, financial condition or results of operations could be negatively affected. In that case, the market price of our common stock could decline, and you could lose all or part of your investment.

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 instrument 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 \$4.8 million for the three months ended March 31, 2010, \$20.0 million in 2009 and \$28.4 million in 2008. At March 31, 2010, we had an accumulated deficit of approximately \$131.0 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 are reliant on the commercial success of our XT-8 System and our diagnostic tests.

Through March 31, 2010, we had primarily placed our XT-8 instruments 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. While we also offer our XT-8 instruments for sale, through March 31, 2010, we had sold only two of our instruments. We expect sales of our diagnostic tests associated with our XT-8 instrument 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 instrument 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 next-generation AD-8 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 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 eight 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

Table of Contents

needs of these laboratories, we can not 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 instrument, our revenues and our ability to achieve profitability 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 our target reference laboratories and hospitals to replace their current testing methods with our XT-8 System and related diagnostic tests and increase usage of our new tests on installed systems. Many factors may affect the market acceptance and commercial success of our molecular diagnostic technology and products, including:

our ability to convince our potential customers of the advantages and economic value of our diagnostic systems and tests over competing technologies and products;

the 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;

our success in training reference and hospital-based laboratories on the proper use of our products;

the willingness of third-party payors to reimburse laboratories that use our diagnostic systems and tests;

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.

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

We primarily place our XT-8 instruments with customers at no direct charge through reagent rental agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years. While we also offer our XT-8 instruments for sale, through March 31, 2010, we had sold only two instruments and 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

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

all of our fixed manufacturing expenses associated with the production of our instruments and test cartridges and therefore we currently

Table of Contents

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 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. As of March 31, 2010, we had 35 instruments actively in use with customers. We recently adjusted our sales strategy by terminating our relationship with a third-party distributor and beginning to build our own direct sales force. 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 and 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.

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 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 instrument will be sufficient to offset our expenses;

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 to attract and retain personnel with the skills required for effective operations; and

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.

Table of Contents

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.

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

We compete with companies that design, manufacture and market already-existing and new molecular diagnostics systems and tests. These competitors include:

companies developing and marketing multiplex molecular diagnostics systems, such as Luminex Corporation and Nanosphere, Inc.;

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 as Roche Diagnostics and Qiagen NV.

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. One or more of our competitors may offer technology superior to ours and render our technology or our current products obsolete, unattractive or uneconomical. Most 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. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable.

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.

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 may have sales that fluctuate on a seasonal basis. 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.

Table of Contents

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

Until such time, if ever, as we can generate substantial product revenues, we will be required to finance our operations with our existing cash resources. We may 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.

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. We outsource manufacturing of our XT-8 instrument and much of the disposable component molding and component assembly for our test cartridges. Our XT-8 instrument 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 is 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 instrument and tests and would have a material adverse effect on our business, financial condition and

Table of Contents

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 fourth quarter of 2010. 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.

We may not be successful in developing our next-generation AD-8 System.

We are developing our next-generation platform, the AD-8 System. We are designing the AD-8 System to integrate sample preparation with our eSensor technology to allow technicians to be able to place a minimally prepared patient sample into our test cartridge and obtain results with no additional steps. The development of the AD-8 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 AD-8 System, which may limit its marketability. In addition, before commercializing the AD-8 System we will be required to obtain regulatory approval for the AD-8 instrument as well as each of the diagnostic tests to be used on the AD-8 instrument, including those tests that previously received approval for use with our XT-8 instrument. If we are unable to successfully develop and obtain regulatory approval for our AD-8 instrument and related diagnostic tests, our business plan will be impaired.

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, in particular Dr. Kayyem or Mr. Kemper, 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.

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.

Table of Contents

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.

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;

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 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 and 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

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

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,

Table of Contents

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.

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. 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. If we experience a sustained material defect or error, this could result in loss or delay of revenues, 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.

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

As of December 31, 2009, we had net operating loss carryforwards of approximately \$62.5 million for U.S. federal tax purposes. These loss carryforwards will expire in varying amounts through 2029. 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 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 this offering. 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 also had non-U.S. net operating loss carryforwards of approximately \$30.4 million as of December 31, 2009. As a result of the Reorganization, there is a significant risk these non-U.S. net operating loss carryforwards may not be utilized.

Our corporate structure may create tax inefficiencies.

As a result of the Reorganization, Osmetech will become a subsidiary controlled by GenMark and a controlled foreign corporation for U.S. federal income tax purposes. GenMark will be required to include in its income certain types of income and investments of Osmetech that otherwise would not be currently taxable under general tax rules. In addition, distributions from the U.S. operating subsidiaries of GenMark may be subject to additional U.S. and foreign income tax withholding and result in lower profits.

Table of Contents

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 AD-8 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.

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 of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic 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 move our operations, including our test cartridge manufacturing operations, to a new facility in Carlsbad, California in the fourth quarter of 2010. 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

Table of Contents

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.

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.

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

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

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

Table of Contents

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.

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

Table of Contents

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 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.

Table of Contents

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

We are exposed to, and may be threatened with, litigation by third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. Some of these third parties 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 property 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. If one of these patents was found to be valid and cover any of our products, proprietary technologies or their uses, we or any collaborator could be enjoined by a court and required to pay damages and could be unable to commercialize our products or product candidates or use our proprietary technologies unless we or they obtained a license to the patent. 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

Table of Contents

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 132 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 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.

Table of Contents

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 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.

Table of Contents

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 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 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. Because 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, 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.

Table of Contents

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.

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 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 and This Offering

The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for investors purchasing common stock in this offering and subject us to litigation.

The offering price for our common stock sold in this offering will be determined based upon negotiations with the underwriters and current market conditions. The public offering price for our common stock may vary from the market price of our common stock at the time of the offering. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

fluctuations in our operating results or the operating results of our competitors;

changes in estimates of our financial results or recommendations by securities analysts;

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

variance in our financial performance from the expectations of securities analysts;

changes in the estimates of the future size and growth rate of our markets;

changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;

Table of Contents

failure of our products to achieve or maintain market acceptance or commercial success;

conditions and trends in the markets we serve;

changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

changes in our pricing policies or the pricing policies of our competitors;

announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or expected sales of our common stock by the holders of our common stock; and

the trading volume of our common stock.

In addition, the stock market in general, the NASDAQ Global Market and the market for diagnostics companies in particular, may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class-action litigation. Class-action litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

An active trading market for our common stock may not develop in the United States, and you may not be able to resell your common stock at or above the public offering price.

Prior to this offering, there has been no public market for our securities in the United States. The ordinary shares of Osmetech have been admitted to trading on the Alternative Investment Market, or AIM, of the London Stock Exchange under the symbol OMH since 2002, and were previously listed on the Official List of the United Kingdom Listing Authority and admitted to trading on the main market of the London Stock Exchange plc. There is currently, however, only a limited volume of trading in ordinary shares of Osmetech on AIM, which limits the liquidity of the ordinary shares on that market. We can not predict when or whether investor interest in our common stock on the NASDAQ Global Market might lead to an increase in market price or the development of a more active trading market or how liquid that market might become. If

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

an active market for our securities does not develop, it may be difficult to sell common stock you purchase in this offering without depressing the market price for our securities, or at all.

Some of our existing stockholders can exert control over us and may not make decisions that are in the best interests of all stockholders.

As of March 31, 2010, officers, directors, and stockholders holding more than 5% of Osmetech's outstanding shares collectively controlled approximately 71.1% of Osmetech's outstanding stock based on their respective beneficial ownership. Immediately after this offering, assuming our officers and

Table of Contents

directors purchase shares with an aggregate purchase price of \$9,650,000 in this offering and Ronin Capital L.L.C purchases 332,238 shares in this offering, these stockholders will beneficially own approximately 59.6% of GenMark's common stock. As a result, these stockholders, if they act together, would be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Accordingly, this concentration of ownership may harm the market price of our shares by delaying or preventing a change in control of us, even if a change is in the best interests of our other stockholders. In addition, the interests of this concentration of ownership may not always coincide with the interests of other stockholders, and accordingly, they could cause us to enter into transactions or agreements that we would not otherwise consider.

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

After this offering, we will have 11,723,512 shares of our common stock outstanding (or 12,413,512 shares if the underwriters exercise their over-allotment option in full). Sales of a substantial number of common stock in the public market following this offering, or the perception that these sales may occur, could cause the market price of our common stock to decline. After the lock-up agreements pertaining to this offering expire, additional holders will be able to sell their common stock in the public market, subject to legal restrictions on transfer. As soon as practicable following completion of this offering, we also intend to file a registration statement covering common stock issued or reserved for such issuance under our share incentive plans. 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. See [Shares Eligible for Future Sale](#) for more information.

We have broad discretion in the use of the net proceeds from this offering, and our investment of these proceeds may not yield a favorable return.

We can not specify with certainty the particular uses of the net proceeds we will receive from this offering, and these uses may vary substantially from our current plans. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in [Use of Proceeds](#). Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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.

Table of Contents

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 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 we may not be able to do so in a timely manner, or at all. 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.

Table of Contents

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.

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 that will be in effect upon the completion of this offering 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.

Table of Contents

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as aim, anticipate, assume, believe, could, due, estimate, expect, goal, intend, may, objective, plan, predict, potential, positioned, should, or other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause such differences include, but are not limited to, the risks described under "Risk Factors," including:

failure to obtain sufficient funding for the continued development and commercialization of our products;

failure to expand our menu of diagnostic tests, including the failure to obtain licenses to additional biomarkers on commercially reasonable terms;

increases in our projected expenditures on sales and marketing, research and development and administrative activities;

less than anticipated growth in the market for diagnostic testing generally and for the tests we are developing or may develop in the future;

failure of our products to gain market acceptance domestically or internationally;

inability to obtain regulatory clearance or approval for any of our products;

changes in the regulatory environment which may adversely impact the commercialization of our new products and result in significant additional capital expenditures;

failure to enter into or maintain successful strategic alliances, which may delay the development or commercialization of our products or may result in significant additional expenditures;

inability to attract or retain skilled personnel for our product development and commercialization efforts;

inability to protect our intellectual property and operate our business without infringing upon the intellectual rights of others, which could result in litigation and significant expenditures;

refusal of third-party payors to reimburse our customers for use of diagnostic systems and tests; and

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

failure to develop our next-generation AD-8 System with the capabilities we intend to offer.

Potential investors and other readers are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See [Where You Can Find More Information](#).

Table of Contents

REORGANIZATION OF OSMETECH PLC

Osmetech plc was incorporated and registered in England and Wales on September 1, 1993. Osmetech's initial business was to exploit the commercial applications of a technology for aroma analysis that emulates the human nose. On June 17, 1994, Osmetech re-registered as a public limited company and its ordinary shares were admitted to trading on the market of the London Stock Exchange. In 1996, Osmetech's ordinary shares were listed on the official list of the United Kingdom Listing Authority, or the Official List, and admitted to trading on the main market of the London Stock Exchange. In 1998, Osmetech applied the technology developed for aroma analysis to healthcare technology to detect the presence of certain infection-causing microorganisms. In 2002, Osmetech delisted from the Official List and Osmetech's ordinary shares were admitted to trading on the Alternative Investment Market of the London Stock Exchange, which is typically the market for smaller quoted companies. In 2005, Osmetech acquired the Clinical Micro Sensors business from Motorola, including the eSensor technology and our eSensor Cystic Fibrosis Genotyping Test, and as a result, Osmetech's assets are located primarily in the United States.

Under English law, it is not possible to change the place of incorporation of Osmetech from one jurisdiction to another so it was necessary to establish GenMark as the new parent company of Osmetech. GenMark was incorporated solely for this purpose and has nominal assets and no operations. Immediately prior to the closing of this offering, Osmetech plc will become a subsidiary controlled by GenMark Diagnostics, Inc., a Delaware company, and GenMark will hold all of the voting power of Osmetech. GenMark will hold all of the outstanding ordinary shares of Osmetech, however certain deferred shares will remain held by the current Osmetech shareholders. The deferred shares are non-transferable and do not entitle the holders to any voting or economic rights in Osmetech other than rights to receive an aggregate nominal payment upon the liquidation of Osmetech.

The establishment of GenMark as the new parent company of Osmetech will be achieved through a scheme of arrangement under Part 26 of the U.K. Companies Act of 2006. Pursuant to the scheme of arrangement, upon approval by Osmetech's shareholders and the English courts, ordinary shares in Osmetech will be cancelled in consideration for (i) the issuance to Osmetech shareholders of shares of common stock in GenMark and (ii) the issuance by Osmetech of new shares to GenMark. Based on the number of outstanding shares, options and warrants of Osmetech as of March 31, 2010, and the 1:230 exchange ratio set forth in the scheme of arrangement, 7,123,512 shares of common stock of GenMark will be issued to holders of Osmetech ordinary shares and 1,184,305 shares of GenMark common stock will be subject to outstanding options and warrants. The scheme of arrangement will have no effect on the manner in which the Osmetech business is conducted. We refer to the transactions contemplated by the scheme of arrangement throughout this prospectus as the Reorganization.

The Reorganization requires the approval of the shareholders of Osmetech, which was obtained on April 27, 2010, and the sanction of the English courts. The Reorganization becomes effective only when a copy of the order of the court approving the scheme of arrangement is delivered to the registrar of companies in England for registration. Osmetech and GenMark have agreed to be bound by the scheme of arrangement and to do what is necessary to facilitate its implementation. The approval of the shareholders of Osmetech and the sanction of the court and the delivery of the court order sanctioning the scheme of arrangement to the registrar of companies in England are conditions to the closing of the offering.

Following the Reorganization and this offering, holders of outstanding options to purchase ordinary shares in Osmetech will hold options to purchase a number of shares of common stock in GenMark equal to the number of shares of GenMark common stock as would have been issued had such options been exercised immediately prior to the Reorganization, and holders of outstanding warrants to purchase ordinary shares in Osmetech will hold warrants to purchase shares of common stock in GenMark equal to the number of shares of GenMark common stock as would have been issued had such warrants been exercised immediately prior to the Reorganization. Our stock option arrangements are discussed in detail below in Executive Compensation Stock Based Incentive Awards.

Table of Contents

USE OF PROCEEDS

We expect to receive approximately \$24.0 million of net proceeds from the sale of our shares of common stock at the initial public offering price of \$6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, or approximately \$27.8 million if the underwriters' over-allotment option is exercised in full.

We intend to use the net proceeds of this offering for the following purposes:

\$10 million for the development of a broad menu of tests;

\$8 million to fund our planned sales and marketing initiatives;

\$3 million to continue to develop our AD-8 System; and

the balance for working capital and other general corporate purposes.

The foregoing expected use of the net proceeds of this offering represents our current intentions based upon our present plans and business condition. The amounts and timing of our actual expenditures may vary significantly and will depend upon numerous factors, including cash flows from operations and the anticipated growth of our business. We will retain broad discretion in the allocation and use of our net proceeds. Pending the allocation of the net proceeds of this offering, we intend to invest the net proceeds of this offering in short-term, interest-bearing obligations, investment grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

Table of Contents

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not currently anticipate declaring or paying cash dividends on our capital stock in the foreseeable future. In addition, pursuant to our Loan and Security Agreement with Square 1 Bank, we are restricted from paying any dividends. We currently intend to retain all of our future earnings, if any, to finance the operation and expansion of our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

Table of Contents**CAPITALIZATION**

The following table summarizes the capitalization as of March 31, 2010:

on an actual historical basis for Osmetech;

on a pro forma basis to give effect to the Reorganization; and

on a pro forma as adjusted basis to give effect to the sale of 4,600,000 shares of our common stock in this offering at the initial public offering price of \$6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, which total approximately \$3.6 million.

You should read the following table in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, Description of Capital Stock and the financial statements of GenMark and Osmetech and related notes appearing elsewhere in this prospectus.

	As of March 31, 2010		
	Osmetech plc Actual	GenMark Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾
Stockholders' equity:			
Ordinary shares, £0.001 (\$0.00158) par value; 1,638,407,754 shares issued and outstanding	\$ 2,581,339	\$	\$
Deferred shares, £0.0099 (\$0.01709) par value; 689,478,300 shares issued and outstanding	11,780,709		
Common Stock \$0.0001 par value; 100,000,000 authorized shares; 7,123,512 shares issued and outstanding, pro forma; 11,723,512 shares issued and outstanding, pro forma as adjusted		712	1,172
Preferred Stock, \$0.0001 par value; 5,000,000 authorized, none issued			
Additional paid-in capital	127,820,232	142,181,568	166,148,743
Accumulated deficit	(130,938,834)	(130,938,834)	(130,938,834)
Accumulated other comprehensive loss	(449,956)	(449,956)	(449,956)
Total stockholders' equity	\$ 10,793,490	\$ 10,793,490	\$ 34,761,125
Total capitalization	\$ 10,793,490	\$ 10,793,490	\$ 34,761,125

⁽¹⁾ GenMark Pro Forma reflects the consummation of the Reorganization on the March 18, 2010 balance sheet of GenMark, which has not changed as of March 31, 2010. Pursuant to the Reorganization, 230 ordinary shares of Osmetech will be exchanged for 1 common share of GenMark, subject to any Osmetech shareholder who is due to receive fractional shares of GenMark common stock in the Reorganization will be entitled to receive a single share of GenMark in lieu of such fractional share. The deferred shares of Osmetech have no rights and will not be exchanged into shares of GenMark common stock. The lower par value of the shares of GenMark common stock compared to the ordinary shares of Osmetech results in the reduction of the GenMark Pro Forma common stock amount to \$712 with the balance allocated into additional paid-in capital. The total value of the stockholders' equity after giving effect to the Reorganization will not change. The Reorganization will take effect following the effectiveness of this registration statement, but prior to the closing of the sale of any securities registered hereunder.

⁽²⁾ Pro Forma As Adjusted reflects the GenMark Pro Forma adjustment and the sale of 4,600,000 shares of GenMark common stock in this offering at the initial public offering price of \$6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The above table excludes the following:

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

221,608,220 (963,514 after giving effect to the 1:230 share exchange) shares of common stock issuable upon exercise of options outstanding as of March 31, 2010, at a weighted

Table of Contents

average exercise price of approximately \$0.03 (\$7.45 after giving effect to the 1:230 share exchange) per common share;

50,782,043 (220,792 after giving effect to the 1:230 share exchange) shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2010, at a weighted average exercise price of approximately \$0.04 (\$8.32 after giving effect to the 1:230 share exchange) per common share; and

2,000,000 shares of common stock which will be available for future grant or issuance under our 2010 Equity Incentive Plan, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2011.

Table of Contents

DILUTION

If you invest in our common stock, your interest in our net tangible book value will be diluted to the extent of the difference between the initial public offering price and the net tangible book value per share of our common stock immediately after the completion of this offering. Dilution results from the fact that the initial public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock after giving effect to the Reorganization.

Our pro forma net tangible book value as of March 31, 2010 was approximately \$10,676,198, or \$1.50 per share. Pro forma net tangible book value per share is determined by dividing the amount of our total tangible assets less our total liabilities by the pro forma number of shares of common stock totaling 7,123,512 shares after giving effect to the Reorganization.

After giving effect to the sale of 4,600,000 shares of common stock in this offering at the initial public offering price of \$6.00 per share, and after deducting underwriting discounts and commissions and our estimated offering expenses totaling approximately \$3.6 million, our pro forma as adjusted net tangible book value as of March 31, 2010 would have been approximately \$34.6 million, or \$2.96 per share.

This amount represents an immediate increase in pro forma net tangible book value of \$1.46 per share and an immediate dilution of \$3.04 per share to new investors. The following table illustrates this calculation on a per share basis:

Initial public offering price per share	\$ 6.00
Pro forma net tangible book value per share of common stock as of March 31, 2010	\$ 1.50
Pro forma increase per share attributable to the offering	1.46
Pro forma as adjusted net tangible book value per share of common stock after this offering	2.96
Dilution per share to new investors	\$ 3.04

If the underwriters exercise an over-allotment option of 690,000 shares in full, our pro forma as adjusted net tangible book value will increase to \$3.10 per share, representing an increase to existing holders of \$1.60 per share, and there will be an immediate dilution of \$2.90 per share to new investors after giving effect to the underwriting discount of 7%.

The following table summarizes, on a pro forma as adjusted basis, as of March 31, 2010, after giving effect to the Reorganization and the sale of 4,600,000 shares in this offering and the pro forma adjustments referred to above, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors at the initial offering price of \$6.00 per share:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	7,123,512	60.8%	\$ 125,274,594	81.9%	\$ 17.59
New investors	4,600,000	39.2	27,600,000	18.1	6.00
Total	11,723,512	100%	\$ 152,874,594	100%	\$ 13.04

Table of Contents

If the underwriters exercise an over-allotment option to purchase 690,000 shares in full, the following will occur:

the pro forma as adjusted percentage of shares of our common stock held by existing stockholders will decrease to approximately 57.4% of the total number of pro forma as adjusted shares of our common stock outstanding after this offering; and

the pro forma as adjusted number of shares of our common stock held by new public investors will increase to 5,290,000, or approximately 42.6% of the total pro forma as adjusted number of shares of our common stock outstanding after this offering.

The above discussion and tables exclude:

963,514 shares of common stock issuable upon exercise of options outstanding as of March 31, 2010, at a weighted average exercise price of \$7.45 per common share;

220,792 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2010, at a weighted average exercise price of \$8.32 per common share; and

2,000,000 shares of common stock available for future grant or issuance under our 2010 Plan, which will become effective upon the closing of this offering, and the annual increases in the number of shares authorized under this plan beginning January 1, 2011.

The preceding discussion and tables assume no exercise of any options and warrants outstanding as of March 31, 2010. If all of our outstanding options and warrants as of March 31, 2010 were exercised, the pro forma as adjusted net tangible book value per share after this offering would be \$3.38 per share, representing an increase to existing holders of \$1.88 per share, and there will be an immediate dilution of \$2.62 per share to new investors.

Table of Contents

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data relates to Osmetech and its consolidated subsidiaries. The selected consolidated statement of operations data of Osmetech presented below for the years ended December 31, 2009, 2008 and 2007 and the selected consolidated balance sheet data of Osmetech as of December 31, 2009 and 2008 have been derived from the audited consolidated financial statements of Osmetech, which have been prepared in accordance with U.S. GAAP, included elsewhere in this prospectus. The selected consolidated financial data as of March 31, 2010, and for the three months ended March 31, 2010 and 2009, have been derived from Osmetech's unaudited condensed consolidated financial statements, included elsewhere in this prospectus, which have been prepared in accordance with U.S. GAAP. Results for the three-month period ended March 31, 2010 are not necessarily indicative of the results of operations that may be expected for our full year performance.

The selected consolidated financial statement of operations data of Osmetech presented below for the year ended December 31, 2006 and the selected consolidated balance sheet data of Osmetech as of December 31, 2007 and 2006 have been derived from unaudited consolidated financial information of Osmetech, not included in this prospectus, and have been prepared by Osmetech in accordance with U.S. GAAP.

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 Osmetech and related notes included elsewhere in this prospectus.

Table of Contents

	Three months ended March 31,			For the year ended December 31,		
	2010	2009	2009	2008	2007	2006
Consolidated Statements of Operations Data:⁽¹⁾						
Revenue:						
Product sales	\$ 384,249	\$ 177,911	\$ 910,527	\$ 559,592	\$ 234,099	\$ 50,500
License revenue	15,015	10,389	87,889	87,500	107,500	41,062
Total revenue	399,264	188,300	998,416	647,092	341,599	91,562
Cost of sales	567,396	1,374,561	4,332,299	3,237,869	2,624,589	2,331,430
Gross loss	(168,132)	(1,186,261)	(3,333,883)	(2,590,777)	(2,282,990)	(2,239,868)
Operating expenses:						
Sales and marketing	1,058,285	553,953	3,181,762	3,393,665	2,220,098	905,962
Research and development	1,453,759	1,430,348	5,633,717	13,423,679	12,554,236	10,606,562
General and administrative	2,167,264	1,457,434	8,288,762	9,632,708	8,895,796	9,781,509
Total operating expenses	4,679,308	3,441,735	17,104,241	26,450,052	23,670,130	21,294,033
Loss from operations	(4,847,440)	(4,627,996)	(20,438,124)	(29,040,829)	(25,953,120)	(23,533,901)
Other (expense) income:						
Foreign exchange (loss) gain	(1,110)	131,766	303,523	504,921		
Interest income						
	4,654	22,697	33,222	420,011	1,715,211	522,293
Total other income	3,544	154,463	336,745	924,932	1,715,211	522,293
Loss before income taxes	(4,843,896)	(4,473,533)	(20,101,379)	(28,115,897)	(24,237,909)	(23,011,608)
Benefit (provision) for income taxes	(5,049)	59,089	138,770	(246,736)	300,214	231,637
Net loss from continuing operations	\$ (4,848,945)	\$ (4,414,444)	\$ (19,962,609)	\$ (28,362,633)	\$ (23,937,695)	\$ (22,779,971)
Net loss per common share from continuing operations (basic and diluted)	\$ (0.003)	\$ (0.005)	\$ (0.02)	\$ (0.12)	\$ (0.12)	\$ (0.14)
Weighted average shares used in net loss per common share	1,636,201,969	891,607,157	1,041,054,350	231,928,699	202,934,689	165,457,028
Unaudited pro forma net loss per common share from continuing operations, basic and diluted ⁽²⁾	\$ (0.68)	\$ (1.14)	\$ (4.41)	\$ (28.13)	\$ (27.13)	\$ (31.67)
Weighted average shares used in unaudited pro forma per share amounts ⁽²⁾	7,113,922	3,876,553	4,526,758	1,008,386	882,325	719,378

⁽¹⁾Osmetech's financial data as of December 31, 2005 and for the year then ended is excluded because we consider it to be of limited value to investors in assessing current operations and financial position for the following reasons: (i) it primarily relates to discontinued operations and Osmetech's molecular testing business, which represents its continuing operations, was not acquired until July 26, 2005; (ii) Osmetech's financial statements for the year ended December 31, 2005 were prepared in accordance with generally accepted accounting principles in the United Kingdom and are not comparable to the financial statements for the years ended December 31, 2009, 2008, 2007 and 2006 which were prepared in accordance with U.S. GAAP; and (iii) Osmetech changed its fiscal-year end in 2005, and as a result, the statement of operations for the period from May 1, 2005 through December 31, 2005, is not, by virtue of its length, readily comparable to annual financial information. Furthermore, we consider that given Osmetech's stage in its development, historical financial data is of limited value to investors primarily due to the fact that the business units that existed prior to the acquisition of its continuing business, the molecular testing business, have now been discontinued. As a result of these factors, preparing the selected financial data for 2005 on a U.S. GAAP basis would entail unreasonable effort and expense and accordingly, this information has been excluded.

⁽²⁾Based on the 1:230 exchange ratio in the Reorganization.

Table of Contents

	As of March 31, 2010	2009	As of December 31, 2008	2007	2006
Balance Sheet Data:					
Cash and cash equivalents	\$ 11,321,012	\$ 16,482,818	\$ 8,822,458	\$ 27,619,715	\$ 13,874,798
Total assets	16,129,662	19,333,477	15,175,215	33,233,621	26,718,736
Long-term liabilities	802,834	795,334	769,237	720,355	339,144
Total liabilities	5,336,172	4,008,659	5,237,946	3,265,933	8,359,361
Accumulated deficit	(130,938,834)	(126,089,889)	(106,127,280)	(77,764,647)	(88,309,444)
Total stockholders' equity	10,793,490	15,324,818	9,937,269	29,967,688	18,359,375

Table of Contents

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 Osmetech and the related notes thereto that appear elsewhere in this prospectus. 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 prospectus.

Overview

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, in Delaware in February 2010, and prior to this offering had no operations. Immediately prior to the closing of this offering, GenMark will acquire all of the outstanding ordinary shares of Osmetech in the Reorganization under the applicable laws of the United Kingdom. As a result of the Reorganization, all of the issued ordinary shares in Osmetech will be 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 will be a subsidiary controlled by GenMark, and the former shareholders of Osmetech will hold shares of GenMark. Any historical discussion under Management's Discussion and Analysis of Results of Operations and Financial Condition relates to Osmetech and its consolidated subsidiaries prior to the Reorganization, except that all share and per share information has been restated on a pro forma basis giving effect 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 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 eight 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 AD-8 System. We are designing the AD-8 System to integrate DNA amplification with our eSensor detection technology to enable technicians using the AD-8 System to be able to place a minimally prepared patient sample into our test cartridge and

Table of Contents

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 AD-8 System to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

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 were approximately \$4.8 million for the three months ended March 31, 2010 and for the years ended December 31, 2009, 2008 and 2007 were approximately \$20.0 million, \$28.4 million and \$23.9 million, respectively. As of March 31, 2010, we had an accumulated deficit of \$131.0 million. Our operations to date have been funded principally through sales of capital stock and sales of Osmetech's 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 instrument 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 instrument for sale, however, through March 31, 2010, we had sold only two XT-8 instruments.

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

Our growth plans focus on both reagent rental agreements and instrument sales of our current XT-8 System and our next-generation AD-8 System that is currently under development. We plan to expand our base of customers and instruments as well as adding more tests for use with our instruments. 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 instruments that have been placed with our customers under a reagent rental agreement, and amortization of licenses related to our test cartridges.

Our XT-8 instruments 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.

Table of Contents

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.

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 instrument and the test cartridges. These expenses also included clinical study expenses incurred in the process of preparing for FDA clearance for these instruments 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 instruments 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.

Gain or Loss on Discontinued Operations

Loss from discontinued operations includes losses from our Gene Sensor business that was terminated in 2007 and from our Critical Care Division. Gain on sale of discontinued operations includes the gain realized upon sale of our Critical Care Division in the first quarter of 2007.

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 include those arising on cash balances held by Osmetech denominated in currencies other than its functional currency, the British pound.

Interest Income

Interest income includes interest earned on our cash and cash equivalents.

Benefit (Provision) for Income Taxes

We account 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. An allowance is provided to reduce deferred tax assets to zero, the amount that management estimates will be recovered.

Table of Contents

Critical Accounting Policies and Significant Judgments and Estimates

Revenue

We recognize revenue from product sales and contract arrangements, net of discounts and sales related taxes. We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured. Where applicable, all revenue is stated net of sales taxes and trade discounts.

We offer customers the choice to either purchase an instrument outright or to receive an instrument free of charge in exchange for an annual minimum purchase commitment for test cartridges. When an instrument is sold, revenue is generally recognized upon shipment of the unit. When an instrument is placed free of charge under a reagent rental agreement, we retain title to the equipment and the instrument remains capitalized on the balance sheet under property and equipment. Under our reagent rental agreements, we retain the right to access or replace the instruments at any time and our customers pay an additional instrument 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 instruments 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 instrument price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on instrument 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 three months ended March 31, 2010, we sold two XT-8 instruments, which represent our first instrument sales.

Revenue related to royalties received from licenses are recognized evenly over the contractual period to which the license relates.

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 instruments, and previously the predecessor eSensor 4800 instruments, and provide these to customers for no charge. Each category of property and equipment is analyzed to determine its useful life. We look at the manufacturers' estimates of useful life and adjusts 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
Instruments at customer location	- 3 years
Office equipment	- 2 - 4 years
Leaseshold 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 instruments 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. Also \$256,909

Table of Contents

of inventory was transferred to machinery and laboratory equipment, as we now intend to place the items with customers for no initial charge.

Impairment of Long-Lived Assets

We assess the recoverability of long-lived assets, including intangible assets and instruments at customer locations by periodically evaluating the carrying value of such assets whenever events or changes in circumstances indicate that the carrying amount of 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 instruments 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 instruments 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 the year ended December 31, 2009, we recorded an impairment against instruments of \$865,389, which was recorded within cost of sales (\$665,718), sales and marketing (\$129,712) and research and development (\$69,959). In the three months ended March 31, 2010, no impairment charges were recorded.

Share-Based Compensation

We have granted our options with an exercise price equal to the closing price of Osmetech's ordinary shares on the Alternative Investment Market, or AIM, of the London Stock Exchange, 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 is calculated using our public company volatility based on our AIM trading prices for a period similar to the expected term of the options.

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 AIM. Although the AIM may be relatively thinly traded, Osmetech's ordinary shares trade on the AIM on a daily basis and reflect prices that investors are willing to pay for the Osmetech shares. Further, in December 2009, we sold 2,086,091 shares of our common stock (after giving effect to the Reorganization) to investors at or near the AIM listed market prices.

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.

Table of Contents

We believe that it is more likely than not that the benefit from certain U.S. federal, U.S. state, and U.K. net operating loss carryforwards will not be realized. In recognition of this risk, we have provided a valuation allowance of approximately \$38.8 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, 2009 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.

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 instruments 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 instruments in the three months ended March 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.

Results of Operations Three months ended March 31, 2010 compared to the three months ended March 31, 2009

Revenue

Revenue increased \$211,000, or 112%, to \$399,000 for the three months ended March 31, 2010 compared to \$188,000 for the three months ended March 31, 2009. The increase in revenue for the 2010 period was driven by an increase in the placement of instruments with customers, resulting in a \$66,000 increase in revenue from our Warfarin Sensitivity Test and a \$40,000 increase in revenue from our Cystic Fibrosis Test. We also sold two XT-8 instruments generating \$95,000 of revenue in the three months ended March 31, 2010. We also had minor sales of two new IUO tests.

Table of Contents

Cost of Sales

Cost of sales decreased \$807,000, or 59%, to \$567,000 for the three months ended March 31, 2010 compared to \$1.4 million for the three months ended March 31, 2009. The decrease was largely due to an impairment of \$549,000 for under-utilized intangible licenses during the three months ended March 31, 2009, and a reduction in direct manufacturing costs of \$164,000.

Sales and Marketing

Sales and marketing expense increased \$504,000, or 91%, to \$1.1 million for the three months ended March 31, 2010 compared to \$554,000 for the three months ended March 31, 2009. The increase was driven by \$393,000 in higher salary, incentive, recruiting costs and higher share based compensation, following a decision to expand the sales force, and increased facility costs.

Research and Development

Research and development expense increased \$23,000, or 2%, to \$1.5 million for the three months ended March 31, 2010 compared to \$1.4 million for the three months ended March 31, 2009. The increase was primarily due to a \$68,000 increase in incentive and share-based compensation expense, which was partially offset by \$46,000 in lower project development expenses.

General and Administrative

General and administrative expense increased \$710,000, or 49%, to \$2.2 million for the three months ended March 31, 2010 compared to \$1.5 million for the three months ended March 31, 2009. The increase was primarily due to \$410,000 for severance payments to Osmetech's former Chief Financial Officer and Vice President of Business Development and \$291,000 in higher share-based compensation expense due to a significant number of new options granted in the quarter ended December 31, 2009.

Foreign Exchange

Foreign exchange loss of \$1,000 for the three months ended March 31, 2010 was \$133,000 lower than the \$132,000 gain for the three months ended March 31, 2009. The loss in the three months ended March 31, 2010 was due to the impact of the strengthening dollar on British pound denominated accounts and the gain in the prior year was due to the settlement by Osmetech of U.S. dollar liabilities during the period as the U.S. dollar weakened against the British pound combined with the benefit of maturing U.S. dollar forward contracts which we held during the period.

Interest Income

Interest and other income declined \$18,000, or 79%, to \$5,000 for the three months ended March 31, 2010 compared to \$23,000 for the three months ended March 31, 2009, due to declining interest rates.

Benefit (Provision) for Income Taxes

A tax provision of \$5,000 was recorded for the three months ended March 31, 2010, compared to a tax benefit of \$59,000 for the three months ended March 31, 2009. During the first quarter of 2010, a tax provision was recorded for minimum state taxes. During the first quarter of 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

Table of Contents

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.

Product Sales

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 instrument. The increase in 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 sale 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 instruments, 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 instruments used in marketing evaluations. During 2009, we changed our estimate of the useful life of instruments 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. We are building our direct sales force during 2010 and expect these costs to increase during 2010 and beyond.

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 instrument development. We also consolidated our Rockland, Massachusetts and Menlo Park, California research facilities into our headquarters in Pasadena, California. From mid- 2008 until mid-2009 our research and development headcount declined by approximately 40 employees.

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 by Osmetech 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.

Table of Contents

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.

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.

Results of Operations 2008 compared to 2007

Revenue

Revenue increased \$305,000, or 89%, to \$647,000 for the year ended December 31, 2008, compared to \$342,000 for the year ended December 31, 2007. The increase was driven primarily by sales of our predecessor Cystic Fibrosis Carrier Detection Test, along with initial sales of our Warfarin Sensitivity Test which was cleared by the FDA in June 2008. Product sales increased \$325,000, or 139%, to \$560,000 for the year ended December 31, 2008 compared to \$234,000 for the year ended December 31, 2007. Product sales consisted solely of test cartridge sales. License revenue declined \$20,000, or 19% to \$88,000 for the year ended December 31, 2008 compared to \$108,000 for the year ended December 31, 2007 due to the timing of license fees.

Cost of Sales

Cost of sales increased \$613,000, or 23%, to \$3.2 million for the year ended December 31, 2008 compared to \$2.6 million for the year ended December 31, 2007. The increase was due to capacity expansion for our manufacturing facilities to support production of our Cystic Fibrosis Genotyping Test as well as higher depreciation on instruments placed with customers.

Sales and Marketing

Sales and marketing expense increased \$1.2 million, or 53%, to \$3.4 million for the year ended December 31, 2008 compared to \$2.2 million for the year ended December 31, 2007. The increase was driven by higher employee-related costs, including salaries, benefits and bonus payments.

Research and Development

Research and development expense increased \$869,000, or 7%, to \$13.4 million for the year ended December 31, 2008 compared to \$12.6 million for the year ended December 31, 2007. The increase in expense was related to the development of potential new tests and was partially offset by lower instrument development costs on our XT-8 System.

General and Administrative

General and administrative expense increased \$737,000, or 8%, to \$9.6 million for the year ended December 31, 2008 compared to \$8.9 million for the year ended December 31, 2007. The increase resulted from costs associated with fund raising activities in 2008, offset by a reduction in share-based compensation charges due to a revision of estimates for achieving performance targets for management long-term incentive plans, and a reduction in bonus payments.

Table of Contents

Foreign Exchange

Foreign exchange gain increased to \$505,000 for the year ended December 31, 2008 compared to zero for the year ended December 31, 2007. The gain was primarily due to U.S. dollar denominated cash balances held by Osmetech at the start of the year and utilized during the year as the U.S. dollar strengthened against the British pound. The functional currency of Osmetech is British pounds.

Interest Income

Interest income declined \$1.3 million, or 76%, to \$420,000 for the year ended December 31, 2008 compared to \$1.7 million for the year ended December 31, 2007, due to lower cash balances and declining interest rates in 2008.

Benefit (Provision) for Income Taxes

A tax provision of \$247,000 was recorded for the year ended December 31, 2008, compared to a tax benefit of \$300,000 for the year ended December 31, 2007. During 2008, a tax provision was recorded due to amendments made to the research and development tax credit claimed in prior periods. During 2007, a benefit was recognized that primarily related to research and development tax credits.

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 March 31, 2010, we had \$10.0 million of working capital, including \$11.3 million in cash and cash equivalents.

Net cash used in operating activities increased \$586,000 to \$4.9 million for the three months ended March 31, 2010 compared to \$4.4 million for the three months ended March 31, 2009 primarily due to an increase in the net loss of \$435,000. This was in part due to a \$466,000 increase in share based compensation during the three months ended March 31, 2010 compared to the three months ended March 31, 2009. Cash usage from the change in accounts payable increased \$411,000 due to lower spending and related payables as of March 31, 2010 compared to March 31, 2009.

Net cash used in investing activities increased \$113,000 to \$137,000 for the three months ended March 31, 2010 compared to \$24,000 for the three months ended March 31, 2009 primarily due to higher capitalized equipment amounts for XT-8 instruments and upgrade parts used for reagent rental programs.

Net cash provided by financing activities for the three months ended March 31, 2010 was \$5,000 from stock option exercises and zero in 2009.

At December 31, 2009, we had \$14.6 million of working capital, including \$16.5 million in cash and cash equivalents. Net cash used in operations declined \$10.7 million to \$15.4 million for the year ended December 31, 2009 compared to \$26.2 million for the year ended December 31, 2008, primarily due to a lower net loss and \$1.2 million of use of inventory. Accounts receivable increased \$51,000 to \$170,000 for the year ended December 31, 2009, compared to \$119,000 for the year ended December 31, 2008, primarily due to higher revenues during the fourth quarter of 2009. Accounts payables, accrued compensation and other current liabilities declined \$1.3 million for the year ended December 31, 2009 primarily due to payments of previously accrued legal and facility renegotiation costs in 2009 as well as lower operating expense and material purchases. Net cash used in investing activities declined \$374,000 to \$1.1 million for the year ended December 31, 2009 compared to \$1.4 million for the year ended

Table of Contents

December 31, 2008 due to slightly lower purchases of capital assets, primarily XT-8 instruments used for reagent rental programs.

Net cash provided by financing activities increased \$14.4 million for the year ended December 31, 2009 to \$24.1 million, compared to \$9.7 million for the year ended December 31, 2008. On June 25, 2009, we issued equity for net proceeds of \$8.4 million. On December 21, 2009, we issued equity for net proceeds of approximately \$15.7 million.

Our primary use of cash in 2009 and the three months ended March 31, 2010 was for operating expenses and cost of sales and we expect our primary future use of cash will be to fund continuing operations as well as development of new tests and our next-generation AD-8 System.

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 March 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.

Pursuant to the terms of the loan and security agreement, we are required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00, however, the ratio is currently not applicable given that we have no bank indebtedness. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to our property, making distributions to our stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount we can borrow under the term loan to license genetic biomarkers to \$500,000. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights. As of March 31, 2010, we had not drawn down any funds under the credit facility or the term loan, however, \$500,000 of the availability under the credit facility was utilized as collateral for an outstanding letter of credit, reducing the availability from \$2.0 million to \$1.5 million. We are currently in compliance with all ratios and covenants.

We believe that our current cash and cash equivalents, our borrowing capacity, and the proceeds of this 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 after this offering 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 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;

Table of Contents

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, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Contractual Obligations

As of December 31, 2009, we had contractual obligations relating to our facilities and equipment leases as follows:

Contractual Obligations	Total	Payments due by period			
		Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating lease obligations ⁽¹⁾	\$ 882,297	\$ 689,330	\$ 192,967	\$	\$

⁽¹⁾Included in these amounts are primarily facilities and various equipment leases. We enter into operating leases in the ordinary course of business with respect to facilities and equipment. 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 instruments from a contract manufacturer. In order to guarantee delivery, we issue purchase orders each 90 day period for delivery of instruments during that period. At December 31, 2009, we had an outstanding purchase order for \$387,000 worth of instruments, for which two-thirds of the costs was recorded in the 2009 financial statements. For the three months ended March 31, 2010, no new purchase agreements for instruments were completed.

Additionally, approximately \$463,000 of unrecognized tax benefits, including accrued interest and penalties of \$81,000, have been recorded as liabilities and we are uncertain as to if or when such amounts may be settled.

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 8,500 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 \$20,723 per month, increasing at a rate of approximately 4% annually thereafter. We are in the process of negotiating a reduction in both the rental rate and term of this lease but there can be no assurance that this lease can be modified. 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

Table of Contents

development project located at 5964 La Place Court, Carlsbad, California, and the project totals 158,733 rentable square feet. Monthly rental payments of \$45,092 commence upon the date of substantial completion of the tenant improvements in the premises and increase 3% annually thereafter. 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.

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. Osmetech is a UK entity and its functional currency is the British pound. 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. The U.S. based subsidiaries of Osmetech use the U.S. dollar as their functional currency. After this offering there will be no material operations outside of the United States which will diminish the extent of any foreign currency exchange risk.

Table of Contents

BUSINESS

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 receipt of an amplified DNA sample, our XT-8 System produces clear and accurate results. Our XT-8 System supports up to 24 test cartridges, of 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 eight 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 AD-8 System. We are designing 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 AD-8 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 pharmacogenetics, or 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.

Table of Contents

Recent Developments

Beginning in the summer of 2009, we initiated a number of actions focused on improving our business and implementing our new strategy, including:

Appointed our New Chief Executive Officer. In August 2009, we retained Jon Faiz Kayyem, Ph.D. as our Chief Executive Officer. Dr. Kayyem is an inventor of our core electrochemical detection technology while he was a Senior Research Fellow at The California Institute of Technology. He founded our predecessor company, Clinical Micro Sensors, and led its development and growth through its acquisition by Motorola, Inc. in 2000 for approximately \$280 million.

Strengthened our Board of Directors and Executive Management. Christopher Gleeson and Kevin C. O'Boyle joined Daryl Faulkner as independent directors, and we retained Steve Kemper as our Chief Financial Officer. Each of these individuals has experience in growing early-stage medical technology companies into high growth health care enterprises. Mr. Gleeson previously served as President, Chief Executive Officer and a Director of Ventana Medical Systems, Inc.; Mr. O'Boyle was the former Chief Financial Officer of NuVasive, Inc.; Mr. Faulkner previously served as President, Chief Executive Officer and Director of Digene Corp.; and Mr. Kemper previously served as the Chief Financial Officer of DexCom, Inc.

Established a New Commercial Organization. In late 2009, we added senior executives to our commercial operations and marketing groups and expanded our direct sales force. At that time, we retained John Bellano as Senior Vice President of Commercial Operations. Mr. Bellano previously served as the Vice President of Sales at Hologic, Inc. and Third Wave Technologies, Inc. With this new organization, we have identified and are focusing our marketing efforts on what we believe are the top 1,000 potential users of our XT-8 System in the United States, primarily high volume national and regional reference laboratories and hospitals.

Rebranded our Operations and Formed a Delaware Parent Company. We are in the process of rebranding our operations as GenMark Diagnostics, Inc. or GenMark. Immediately prior to the closing of this offering, GenMark will acquire all of the outstanding ordinary shares of Osmetech plc, or Osmetech, in the Reorganization under the applicable laws of the United Kingdom. As a result of this transaction, Osmetech will become a subsidiary controlled by GenMark, and the former shareholders of Osmetech will hold shares of GenMark.

Adopted a New Market-Driven Product Development Strategy. We changed our product development strategy to accelerate development of a large menu of multiplex diagnostics tests for use on our XT-8 instrument. In addition to our FDA-cleared Cystic Fibrosis Genotyping, Warfarin Sensitivity and Thrombophilia Risk Tests and our Respiratory Viral Panel Test, which is currently labeled for IUO, we are developing or designing eight additional tests for our XT-8 instrument in the areas of pharmacogenetics, genetic diseases, infectious diseases and oncology. We are also developing our next-generation sample-to-answer diagnostic system, the AD-8 System, which we believe will expand the potential customer base for our products.

Streamlined Operations. We closed our facilities in Rockland, Massachusetts, Duxbury Massachusetts, Menlo Park, California and the United Kingdom to reduce our operating costs and streamline our operations. To further improve our operations, we intend to close our two facilities in Pasadena, California and combine our manufacturing, research and development and administrative operations into a single facility in Carlsbad, California in the fourth quarter of 2010.

Table of Contents

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 for our tests. We intend to explore other 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 the appropriate biomarkers that have shown correlations to diseases or drug sensitivity.

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 new commercial organization to drive placements of our XT-8 System. We anticipate expansion of our installed base of customers will drive sales of our test cartridges, from which we anticipate generating the majority of our revenues.

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 Next-Generation AD-8 System. We are developing our AD-8 System to provide all the customer benefits of our XT-8 System while also integrating automated DNA amplification. This feature will eliminate the need for time consuming and complex sample preparation steps and allow technicians to place a minimally prepared patient sample into our test cartridge. We have already demonstrated feasibility of direct sample-to-answer detection on an AD-8 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 our opportunities to leverage our intellectual property position in detection technologies through out-licensing or the establishment of partnerships.

Our Market Opportunity

The U.S. market for molecular diagnostics was estimated to be \$1.9 billion in 2009 and is anticipated to reach \$3.4 billion in 2014 according to L.E.K., a market research firm. Molecular diagnostics generally refers to the detection and measurement of DNA or RNA biomarkers to diagnose disease and

Table of Contents

to optimize the treatment of patients. We believe that the following factors, among others, are contributing to the growth of this market:

Expansion of Genetic Testing for Disease Predisposition. Advances in the understanding of the relationship between an individual's genetics and disease have led to increased reliance on molecular diagnostic testing for inherited diseases such as cystic fibrosis and thrombophilia. We expect new molecular diagnostic tests will be required as researchers continue to discover new relationships between genetics and disease, new medical treatments are developed and as professional societies set guidelines regarding genetic disease and the role of genetic counseling in the interpretation of the results of these tests.

Adoption of FDA-Cleared Molecular Diagnostic Testing Methods. The FDA recommends that laboratories and hospitals use FDA-cleared molecular diagnostic tests when these tests are available, rather than tests known as "home-brew tests" or laboratory developed tests, or LDTs, that are not submitted to the FDA for approval. LDTs are broadly used by reference laboratories and hospitals to perform molecular diagnostic tests and are subject to strict regulatory requirements. As a result, we believe reference laboratories and hospitals will look to replace their existing LDTs and non-FDA-cleared molecular diagnostic tests with FDA-cleared tests as they become available.

Advances in Cancer Therapy. Tailoring treatments to an individual's tumor type and genetics is an important trend in cancer therapy. The FDA has required or recommended that molecular diagnostic tests be performed before administration of certain drugs, such as Herceptin, Erbitux and Vectibix. We believe molecular diagnostic testing to determine an individual's response to certain cancer therapies will drive demand for molecular diagnostics.

Increased Demand for Infectious Disease Diagnostic Panels. Different disease pathogens can produce similar symptoms, but with vastly distinct courses of disease progression and required medical treatment responses. For example, pneumonia caused by Mycoplasma may resolve without treatment, while pneumonia caused by Legionella will generally require aggressive medication and hospitalization. In order to improve patient care, we believe physicians are increasingly requesting infectious disease diagnostic panels to be performed. According to L.E.K., the market for molecular diagnostic testing of infectious diseases in the United States was estimated to be \$1.1 billion in 2009. We intend to address the small and emerging multiplex diagnostic segment of this market which the Company's management estimates to be in the range of \$50 million to \$100 million.

Advances in Personalized Medicine. Tailoring treatments to an individual's genetic profile—called personalized medicine or pharmacogenetics—is emerging as an important trend and will drive demand for molecular diagnostic testing. Pharmaceutical companies, clinical researchers and pharmacy benefit managers are screening drugs for varied toxicity, dose response and efficacy among individuals with different genetic profiles. Additionally, regulating agencies continue to revise drug labels to improve safety and efficacy. Because these industry developments may improve clinical outcomes and reduce costs for third-party payors, we believe adoption of these tests will become more widespread in a managed care environment.

Limitations of Existing Diagnostic Products and Technologies

Scientists have developed a variety of genomic analysis methods, including DNA sequencing, gene expression analysis and genotyping, to measure genetic biomarkers and detect diseases. These analytical methods are performed using various molecular diagnostic testing technologies, the most common being polymerase chain reaction, or PCR, which involves amplifying, or generating exponential copies of, the DNA sequence in question and then detecting the DNA with the use of fluorescent dyes.

The first commercially used molecular diagnostic tests were "home brew tests" or LDTs developed by reference laboratories and large hospital-based laboratories. LDTs, which are still broadly used today,

Table of Contents

are generally single-purpose tests that involve a number of complex, manual procedures. To perform these tests, laboratories are required to employ highly skilled technicians and maintain specialized laboratory facilities and equipment. As the market for molecular diagnostic tests expanded, a number of companies developed and began offering dedicated instrumentation and commercialized testing systems for specific genetic biomarkers and diseases. These commercialized testing systems, as well as LDTs, are characterized by the following limitations:

Limited Menu of Diagnostic Tests. Existing LDTs are typically custom designed for one specific genetic biomarker or disease. In addition, commercialized testing systems currently offer only a limited number of molecular diagnostic tests for use with such systems. As a result, laboratories need numerous LDTs and commercialized testing systems to offer their physician and hospital clients with a range of molecular diagnostic testing options.

Inability to Multiplex. In many cases, testing for multiple genetic biomarkers may be necessary to diagnose a disease, differentially identify infectious agents or evaluate the appropriate treatment options for a patient. Many LDTs and commercialized testing systems lack the ability to multiplex, or test for multiple genetic biomarkers at the same time on a single patient sample. As a result, the laboratory must perform multiple, separate tests on a sample. Serial testing is time-consuming and expensive and significantly increases the amount of time and sample needed to complete a diagnostic analysis.

Poor Laboratory Workflow. LDTs and commercialized testing systems generally do not permit laboratories to initiate new tests while other tests are in progress. As a result, laboratories are required to batch process molecular diagnostic tests. To help control costs, laboratories may only run a particular molecular diagnostic test on an infrequent basis. In addition, LDTs and commercialized testing systems require significant sample preparation and additional washing steps, which adds to the complexity and time required to complete a molecular diagnostic test. Many of them also involve optical systems, robotics and complicated moving parts that must be frequently calibrated and are subject to maintenance and repair issues.

Risk of Human Error. Many LDTs and commercialized testing systems generally require technicians to perform a series of complex manual procedures which may lead to contamination. Commercialized testing systems only automate certain steps in the testing process, and technicians are often required to use multiple instruments or manual processes in sequence to generate results. The handling of samples and the multiple manual procedures required by existing products can lead to increased risk of sample contamination and human error. In addition, LDTs and many commercialized testing systems require the operator to interpret results, which increases the potential for human error and leads to problems related to repeatability of results.

Intensive Resource Requirements. Laboratories are required to employ and train highly-skilled technicians and dedicate significant capital, labor and laboratory space to conduct molecular diagnostic tests. In fact, many of the multiplex LDTs and commercialized testing systems currently used by national reference laboratories are so specialized that we believe only a limited number of their sites have the capability to perform these test. As a result, we believe national reference laboratories do not have the ability to perform their entire menu of multiplex tests across all of their locations, and smaller hospital-based laboratories face significant hurdles to initiate molecular diagnostic testing at limited volumes.

Shifting Regulatory Environment. A significant number of molecular diagnostic tests, including LDTs as well as commercialized testing systems, have not been submitted for FDA clearance. The FDA has imposed regulatory requirements on laboratories that use LDTs or other non-FDA-cleared commercialized testing systems, including the requirement to comply with CLIA standards. In the future, the FDA may restrict the use of LDTs and

Table of Contents

non-FDA-cleared molecular diagnostic tests unless the laboratories comply with medical device requirements, including the FDA's Quality Systems Regulations and 510(k) clearance or PMA approval requirements.

These limitations have created a laboratory model for molecular diagnostic testing that is complex, inefficient and inaccessible to a large segment of reference laboratories and hospitals.

Our Solution

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 and self-contained, disposable test cartridges. The XT-8 System is user-friendly, intuitive, essentially maintenance-free 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 eight 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 intend to introduce two to four new tests annually. 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.

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.

Table of Contents

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 Products

Our XT-8 System

Our FDA-cleared XT-8 System is an automated, multiplex molecular diagnostics workstation that provides a wide range of diagnostic testing capabilities in pharmacogenetics, genetic and infectious diseases and oncology. Our XT-8 System consists of a compact bench-top workstation with an integrated touch screen computer and self-contained, disposable test cartridges. 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' instruments, 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 barcode wand or on-screen keyboard and inserts the test cartridge into an open slot on the instrument. 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 30 minutes to complete, and the test results can be viewed on the built-in touch screen monitor or printed out and reported through the laboratory's computer information system.

Table of Contents

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
<i>Our Test Menu</i>	

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, 2009, sales of our Cystic Fibrosis Genotyping Test represented approximately 67% of our revenues, and sales of our Warfarin Sensitivity Test represented approximately 20% 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.

Table of Contents

According to the Medco-Mayo Warfarin Effectiveness Study, there were approximately two million new patients 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.

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 risk 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 intend to initiate clinical studies on the new RVP panel in 2010 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 eight 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 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

Table of Contents

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.

Plavix's initial patents expire in 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.

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.

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 instrument 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 stage. These include: Lower Respiratory Tract Infections (LRTI); Central Nervous System Infections (CNS); Hepatitis C Virus Genotyping (HCVg); and Human Papillomavirus Genotyping (HPVg).

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 instrument 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.

Table of Contents

Our AD-8 System

We are developing our next-generation testing system, the AD-8 System, to integrate DNA amplification with eSensor DNA detection. We are designing the AD-8 System to allow a technician to place a minimally prepared patient sample into our test cartridge, reducing the complex and time consuming sample preparation process before testing. The AD-8 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 DNA amplification. We believe this advancement will make our eSensor technology attractive to the broad range of institutions that currently lack the technical or economic resources to perform molecular diagnostic testing. We believe the AD-8 System may expand our target user base from 1,000 to over 5,000 potential laboratories and hospitals in the United States.

The AD-8 System is currently in development with technical feasibility completed using diluted blood in our Warfarin Sensitivity Test. The AD-8 System leverages the base technology and system hardware from our XT-8 System to reduce risk and accelerate the development of the DNA amplification feature. While the initial approach relies upon an amplified DNA patient sample, the design of the system addresses the intended evolution of the platform towards an integrated sample-to-answer system capable of using an unprocessed patient sample. We believe a minimally prepared patient sample combined with the integrated amplification and multiplex detection of the AD-8 System will offer significant 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

Table of Contents

slot in our XT-8 instrument. 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, through a microfluidic channel when inserted into the XT-8 instrument. 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 Instrument. Our XT-8 instrument is a multiplex workstation that has a modular design consisting of a base module and up to three test cartridge-processing towers of eight cartridge slots each. The test cartridge slots operate independently of each other allowing up to 24 test cartridges to be loaded at one time, with the remaining slots available for use at any future time while the instrument 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

Table of Contents

between the instrument and the cartridge. The pneumatic pumping enables recirculation of the hybridization solution allowing the target DNA and the signal probes to efficiently hybridize with the complementary capture probes on the electrodes. The diaphragm pump in the test cartridge is connected to a pneumatic source from the XT-8 instrument and provides unidirectional pumping of the hybridization mixture through the microfluidic channel during hybridization.

The base module controls each processing tower, provides power and stores and analyzes data. The base module includes an intuitive touch-screen interface. 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 instrument with relatively few moving parts. In contrast, conventional microarray systems require robotic instrumentation to automate multistage fluidic handling processes. As a result, these instruments are often bulky,

Table of Contents

complicated and expensive and require frequent calibration and maintenance. Our XT-8 System, for example, requires no calibration and virtually no maintenance and is self-contained in a small footprint of approximately 16-by-16 inches in its standard configuration.

Cost-Effective Development. The use of electrochemical technology allows our XT-8 System to leverage third-party advances in microelectronics such as miniaturization and manufacturing efficiencies. Many electronic components associated with our core processes are produced in large volumes at low cost and size for use in numerous fields including automotive, aerospace, information technology and medical devices. By avoiding the use of 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 instrument. 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 March 31, 2010, we had 17 employees focused on research and development. We currently perform our research and development activities at our 25,000 square foot facility in Pasadena, California. In the fourth quarter of 2010, we expect to move our research and development activities to our new 31,000 square foot headquarters in Carlsbad, California. Our research and development expenditures were approximately \$1.5 million for the three months ended March 31, 2010, approximately \$5.6 million for the year ended December 31, 2009, approximately \$13.4 million for the year ended December 31, 2008, and approximately \$12.6 million for the year ended December 31, 2007. This reduction in research and development expenses was due to the completion of our XT-8 System in 2009.

In addition to expanding the diagnostic test menu for our XT-8 System and developing our AD-8 System, our research and development team are 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.

Table of Contents

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.

Manufacturing

We manufacture our proprietary test cartridges and ancillary reagents at our approximately 8,500 square foot facility in Pasadena, California. We have received ISO 13485:2003 certification for our facility, which is the basic quality certification for medical device manufacturers, service providers and distributors. In the fourth quarter of 2010, we plan to move our manufacturing operations to our new 31,000 square foot headquarters in Carlsbad, California. 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 instrument, 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 instrument 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

We recently established a national direct sales and marketing organization consisting of seven sales representatives, one sales director, one marketing manager and one product manager. Our representatives typically have extensive experience in molecular diagnostics and a network of contacts with reference laboratories and hospitals within their respective territories.

Our initial target market is the top 1,000 national and regional reference laboratories and research based hospitals in the United States that we believe will be high volume customers and who will benefit from our eSensor technology. We utilize our representatives' knowledge along with market research databases to target highly qualified customers. We tailor our sales approach based on the specific needs and buying criteria of each customer segment.

Our sales cycle typically includes customer evaluations and validations of our products. Upon successful validation, our customers can acquire our XT-8 System and diagnostic tests in the following ways:

Reagent rentals. An XT-8 instrument is placed at a customer location and the customer commits to purchase a certain minimum volume of test cartridges annually at a price that is intended to allow us to recover the manufacturing cost of the XT-8 instrument.

Table of Contents

Capital purchases. The total cost of the XT-8 instrument is paid for by the customer up front; however, the customer is still required to purchase an annual minimum volume of test cartridges. Through March 31, 2010, we had sold two XT-8 instruments to customers.

Our reagent rental agreements do not allow the customer to require us to repurchase the instrument or test cartridges and typically do not provide for any cancellation rights by the customer. However, the reagent rental agreements allow us to remove, change or upgrade the XT-8 instrument at any time.

Our sales and marketing team also provides customer service for order fulfillment, technical service and product support and distribution logistics. We plan to utilize and expand this organization as our installed customer base grows, as our diagnostic test menu expands, and to support the launch of our AD-8 System.

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 molecular diagnostics through out-licensing or the establishment of partnerships.

During 2009 and 2008, 38% and 54% of our revenues, respectively, were attributed to our three largest customers during the year, each of whom constituted more than 10% of our revenues. We do not believe the loss of one or more of these large customers would materially impact our ability to generate and grow our revenues because our revenues for these years were insignificant relative to our sales and operating expenses and we intend to significantly expand our customer base in the near future.

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., Hologic, Inc., Luminex Corporation, Nanosphere, Inc., Qiagen NV and Roche Diagnostics. Our diagnostic tests also face competition with the LDTs 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 and future products. As of March 31, 2010, our patent portfolio included 94 U.S. patents, 38 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. Motorola initially purchased the Clinical Micro Sensors business for \$280 million.

Table of Contents

We believe that our patent portfolio and licenses provide us intellectual property protection 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.

License Agreements

XT-8 System

California Institute of Technology. We have an exclusive license from the California Institute of Technology to patents and patent applications related to nucleic acid-mediated electron transfer technology. The license grant is worldwide, fully paid-up, and extends until the last of the underlying patents expires in June 2017. The agreement is also conditioned on us paying all associated patent maintenance and prosecution fees. Either party may terminate the license agreement upon a material breach by the other party subject to a cure period. We may terminate the license agreement for any reason upon 60 days written notice.

Harvard University. We have licensed from Harvard University exclusive worldwide rights to technology relating to self-assembling monolayers, or SAMs, and nucleic acid devices and methods. The license agreement provides for an upfront payment which has been paid, a maintenance/minimum annual fee which is creditable against royalties, royalties on net sales of products incorporating the underlying patents, payment of a fraction of sublicensing upfront and milestone fees and royalties and payment of all prosecution costs and maintenance fees. The license extends for the life of the underlying patents, the last of which expires in January 2017. The license agreement is terminable by Harvard upon certain events, including our insolvency or bankruptcy, our breach of the license agreement or our underreporting or underpayment of royalties, some of which are subject to a cure period. If it terminates the license agreement, Harvard may, in its discretion, have a right in all sublicenses assigned for its benefit. We may terminate the license agreement for any reason upon 90 days advance written notice. Harvard retains certain rights under this license.

Diagnostic Test Content Licenses

Marshfield Clinic. In October 2007, we exclusively licensed from Marshfield Clinic, or Marshfield, worldwide rights to a genetic marker, CYP 4F2, that has been shown to correlate with warfarin sensitivity. A patent cooperation treaty, or PCT, application and United States utility patent application are currently pending. We paid a one-time upfront fee upon execution of the license and are required to pay quarterly net royalties, with a minimum annual royalty which began in 2009 that is subject to certain conditions. The agreement also requires sharing of sublicense royalties and a portion of any upfront fees we receive under a sublicense. The agreement extends for the life of any patent or patents issuing from the underlying patents and the pending application, which are expected to expire in October 2028. The agreement automatically terminates upon our nonpayment of royalties for more than eight

Table of Contents

calendar quarters. In addition, Marshfield Clinic may terminate the agreement upon our failure to semi-annually produce and report acceptable commercial development efforts, our bankruptcy or insolvency or our otherwise breaching the license agreement, subject to a cure period. We have the right to terminate the license agreement for any reason upon 90 days' advance written notice. The license agreement also provides for option rights to additional markers that may be discovered by Marshfield during the term of the license agreement.

University of Washington. We have licensed, on a non-exclusive basis, from the University of Washington a biomarker relating to warfarin sensitivity that we use in our Warfarin Sensitivity Test. We paid an upfront fee upon execution of this license agreement. We are required under this license agreement to pay a quarterly royalty on net sales of products incorporating the underlying claims and to pay variable minimum royalties and a pro-rata share of ongoing patent prosecution and maintenance costs. This license extends for the life of the patent, which expires in 2024 or 2025. The license agreement is terminable upon a material breach by the other party of its obligations under such license agreement, subject to a cure period, or our becoming subject to receivership, winding up or bankruptcy. We may terminate the license agreement for any reason upon 60 days' advance written notice to the University of Washington.

Johns Hopkins University. We acquired a non-exclusive license from Johns Hopkins University in April 2006 to utilize patented mutations in the cystic fibrosis gene in our cystic fibrosis genotyping test cartridges. The agreement required a one-time upfront payment coupled with an annual minimum royalty creditable against actual royalties, to be reported quarterly. The license expires upon expiration of the licensed patent in 2012, Johns Hopkins University retains the right to terminate upon material breach not cured within 60 days, and we retain the right to terminate for any reason upon 90 days' written notice.

Hospital for Sick Children. In March 2006, we acquired a non-exclusive license from HSC Research and Development Limited Partnership, or HSC, to the use of various other mutations in the cystic fibrosis gene. The agreement required a one-time upfront fee, coupled with an escalating annual minimum royalty creditable against quarterly royalty payments for the life of the patent. The agreement remains in effect until the last to expire of the underlying patents in 2016. HSC may terminate for material breach not cured within 60 days, and we may terminate upon 90 days' written notice. There is also a clause prohibiting assignment of the license by licensee to another without the express written consent of HSC.

University of Michigan. In March 2006, we acquired a non-exclusive license from the University of Michigan, or UM, and HSC to utilize the cystic fibrosis genes. A one-time upfront was paid and escalating annual license maintenance fees are required against which running royalties are credited. The agreement remains in effect until the last to expire of the underlying patents in 2013. HSC/UM may terminate upon a material breach not cured within 60 days, and we may terminate upon 90 days' written notice. There is also a clause prohibiting assignment of the license by licensee to another without the express written consent of HSC/UM.

Roche Molecular Systems, Inc. We have a non-exclusive license from Roche Molecular Systems, Inc. to utilize a form of chemically modified thermostable DNA polymerase that is a component in some of our FDA-cleared commercial products. We paid a one-time upfront fee for this and are obliged to pay quarterly running royalties on net sales. The agreement remains in effect until the last to expire of the underlying patents in 2016. Either party may terminate the license agreement upon a material breach of the license agreement by the other party, subject to a cure period, or upon the filing for bankruptcy of the other party.

Out-Licenses of Our Intellectual Property

We have granted an exclusive license for the use of our electrochemical technology for certain applications outside of DNA and RNA diagnostic testing, and a non-exclusive sub-license to our SAM

Table of Contents

technology for use in those applications to Ohmx. Pursuant to those license agreements, Ohmx is required to pay us minimum royalty payments each year and quarterly royalties. We have also granted a non-exclusive sub-license to Minerva Biosciences of our SAM technology, relating to certain other applications outside of DNA and RNA diagnostics testing. Minerva is required to pay us a license fee, annual minimum royalties and quarterly royalties on net sales of products using this technology.

Loan Agreement

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 March 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. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights.

Government Regulation

The design, development, manufacture, testing and sale of our diagnostic products are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and foreign regulatory agencies.

Regulation by the FDA

In the United States, the Federal Food, Drug, and Cosmetic Act, or FDCA, FDA regulations and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. The FDA regulates the design, manufacturing, servicing, sale and distribution of medical devices, including molecular diagnostic test kits and instrumentation systems. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

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

Table of Contents

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.

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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 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 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. 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.

Table of Contents

Fraud and Abuse Regulations

We are subject to numerous federal and state health care anti-fraud laws, including the federal anti-kickback statute and False Claims Act, that are intended to reduce waste, fraud and abuse in the health care industry. These laws are broad and subject to evolving interpretations. They prohibit many arrangements and practices that are lawful in industries other than health care, including certain payments for consulting and other personal services, some discounting arrangements, the provision of gifts and business courtesies, the furnishing of free supplies and services, and waivers of payments. In addition, many states have enacted or are considering laws that limit arrangements between medical device manufacturers and physicians and other health care providers and require significant public disclosure concerning permitted arrangements. These laws are vigorously enforced against medical device manufacturers and have resulted in manufacturers paying significant fines and penalties and being subject to stringent corrective action plans and reporting obligations. We must operate our business within the requirements of these laws and, if we were accused of violating them, 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.

Facilities

We have two facilities located in Pasadena, California, including our approximately 8,500 square foot manufacturing facility and our approximately 25,000 square foot research and development and administrative facility. The lease on our manufacturing facility expires in July 2011 and the lease on our research and development and administrative facility expires in June 2010. In February 2010, we leased a new 31,000 square foot headquarters in Carlsbad, California. We are currently in the process of making leasehold improvements on the facility and we anticipate the facility will be ready for occupancy in the fourth quarter of 2010.

Employees

As of March 31, 2010, we had 63 full-time employees. Of these employees, 17 were in research and development, 16 were in manufacturing and operations, 3 were in quality control and quality assurance, 15 were in sales and marketing and 12 were in general and administrative functions. We have never had a work stoppage, and none of our employees are covered by collective bargaining agreements or represented by a labor union. We believe our employee relations are good.

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.

Table of Contents

History and Development

In August 2009, we retained Jon Faiz Kayyem, Ph.D. as our Chief Executive Officer. Dr. Kayyem is an inventor of our core intellectual property. He founded our predecessor company, Clinical Micro Sensors, in 1995 and led the development and growth of that company through its acquisition by Motorola, Inc. in 2000 when it was sold for approximately \$280 million. Motorola invested additional resources in the development of our diagnostic technology until 2005, when Motorola sold the Clinical Micro Sensors business to Osmetech forming the basis for Osmetech's current business.

General Information

The address of our principal place of business is 757 S. Raymond Avenue, Pasadena, CA 91105. We also maintain a website at www.genmarkdx.com. The information contained in or that can be accessed through our website is not a part of this prospectus.

Table of Contents**MANAGEMENT****Directors and Officers**

The following table provides information regarding the directors and officers of GenMark Diagnostics, Inc., including their ages and positions:

Name	Age	Position
Jon Faiz Kayyem, Ph.D.	46	President and Chief Executive Officer
Steven Kemper	55	Chief Financial Officer, Treasurer and Secretary
John Bellano	41	Senior Vice President, Commercial Operations
Pankaj Singhal, Ph.D.	39	Senior Vice President, Product Development and Manufacturing
Christopher Gleeson	60	Chairman of the Board
Daryl J. Faulkner	61	Director
Kevin C. O Boyle	54	Director

The business address for our directors and senior management is c/o GenMark Diagnostics, Inc., 757 S. Raymond Avenue, Pasadena, CA 91105.

Jon Faiz Kayyem, Ph.D. Dr. Kayyem has served as President and Chief Executive Officer and Director of GenMark Diagnostics, Inc. since March 2010. Dr. Kayyem was appointed to the board of directors of Osmetech in January 2009 as Chairman, becoming Vice Chairman of Osmetech in August 2009 and assuming the role as President and Chief Executive Officer of Osmetech in August 2009. 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, or Caltech. Dr. Kayyem remained at Caltech as a Senior Research Fellow until 1995, when he founded Clinical Micro Sensors to commercialize technical innovations he developed while at Caltech. In 2000, Clinical Micro Sensors was sold to Motorola, Inc. for approximately \$280 million, and subsequently purchased by Osmetech plc in 2005. In 2004, Dr. Kayyem left Clinical Micro Sensors and co-founded the biotechnology fund management company, Efficacy Capital Limited, where he served as managing partner until September 2009. We believe Dr. Kayyem is qualified to serve on our board of directors based on his executive experience at Clinical Micro Sensors where he led the development and growth of the company through its acquisition by Motorola, Inc.

Steven Kemper. Mr. Kemper has served as Chief Financial Officer, Treasurer and Secretary of GenMark Diagnostics, Inc. since March 2010. Since November 2009, Mr. Kemper has served as Senior Vice President, Finance of Osmetech Molecular Diagnostics, a wholly owned subsidiary of Osmetech plc. From December 2007 to June 2009, Mr. Kemper served as Chief Financial Officer of The Active Network, a supplier of online registration services for recreational events. From March 2003 to July 2007, Mr. Kemper served as the Chief Financial Officer of DexCom, Inc., a medical device company focused on the design, development and commercialization of continuous glucose monitoring systems. From 1996 to present, Mr. Kemper also served as President of Pacific Financial Consulting, a financial consulting enterprise. Mr. Kemper also served as a director of Open Energy Corp. from November 2007 to October 2008. Mr. Kemper received a B.A. from the University of California, San Diego, an M.B.A. from Loyola Marymount University, an M.S. from San Diego State University and is a licensed C.P.A.

John Bellano. Mr. Bellano has served as Senior Vice President, Commercial Operations of GenMark Diagnostics, Inc. since March 2010, and as Senior Vice President, Commercial Operations of Osmetech

Table of Contents

Technology Inc., a wholly owned subsidiary of Osmetech plc, since December 2009. From July 2008 until December 2009, Mr. Bellano was Vice President of Sales for Hologic, Inc., a developer, manufacturer and supplier of medical imaging systems and diagnostic and surgical products. From February 2005 until its acquisition by Hologic in June 2008, Mr. Bellano was Vice President of Sales and a member of the executive team of Third Wave Technologies Inc., a provider of DNA and RNA analysis products to clinical, research and agricultural customers. From February 2000 to February 2005, Mr. Bellano held various positions within the molecular group of Roche Diagnostics, the diagnostics division of Roche Pharmaceuticals. Mr. Bellano received a B.S. in sales and marketing from Desales University.

Pankaj Singhal, Ph.D. Dr. Singhal joined Clinical Micro Sensors in 2000 and remained with Osmetech following Osmetech's acquisition of Clinical Micro Sensors from Motorola in 2005. Dr. Singhal has served as Senior Vice President, Product Development and Manufacturing of GenMark Diagnostics, Inc. since March 2010. From May 2008 through March 2010, Dr. Singhal served as Chief Operating Officer of Osmetech Technology Inc., a wholly owned subsidiary of Osmetech plc, where he led the operations team that commercialized the original eSensor technology. 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. He 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, and has obtained multiple patents in these areas. He is also a Motorola-certified Six Sigma black belt in the areas of manufacturing and design development.

Christopher Gleeson. Mr. Gleeson has served as Chairman of the Board of GenMark Diagnostics, Inc. since March 2010 and as Chairman of the Board of Osmetech plc since July 2009. Mr. Gleeson was formerly President, Chief Executive Officer and a Director of Ventana Medical Systems, Inc., a leading supplier of automated diagnostic systems to the anatomical pathology market where he served from 1999 to February 2008. Following the acquisition of Ventana by Roche Diagnostics in February 2008 for \$3.4 billion, 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. We believe Mr. Gleeson is qualified to serve on our board of directors based on his executive experience in the medical device and molecular diagnostics industries as described above.

Daryl J. Faulkner. Mr. Faulkner has served on the board of directors of GenMark Diagnostics, Inc. since March 2010. Mr. Faulkner was appointed to the board of directors of Osmetech plc in August 2008, serving as Non-Executive Chairman until December 2008. Mr. Faulkner is currently Executive Chair and Chief Executive Officer of AspenBio Pharma, an emerging biotechnology company engaged in the research, development, manufacture, and licensing of novel diagnostics and drugs, a role which he began in January 2009. From August 2008 to January 2009, Mr. Faulkner served as a consultant to Qiagen NV, a leading provider of innovative sample and assay technologies and products, in connection with its integration of Digene Corp., a developer of gene-based diagnostic tests acquired by Qiagen in August 2007. Mr. Faulkner had served as President and Chief Executive Officer and a director of Digene from December 2006 until consummation of Qiagen's acquisition of Digene. From 1998 until March 2006, Mr. Faulkner served in several executive roles at Invitrogen Corp., a life sciences company, including Senior Vice President, Business Segment Management from 2003 until March 2006. Mr. Faulkner received a B.S. in Industrial Relations from the University of North Carolina, Chapel Hill and an M.A. in Business Management from Webster University. We believe Mr. Faulkner is qualified to serve on our board of directors based on his executive experience in the medical device and molecular diagnostics industries as described above.

Table of Contents

Kevin C. O Boyle. Mr. O Boyle has served on the board of directors of GenMark Diagnostics, Inc. since March 2010. Previously he served as the Chief Financial Officer of NuVasive, Inc., a medical device company focused on the design, development and marketing of products for the surgical treatment of spine disorders, from January 2003 to December 2009 and the Executive Vice President of NuVasive from December 2004 to December 2009. Prior to that time, Mr. O Boyle served in various positions during his six years with ChromaVision Medical Systems, Inc., a publicly traded medical device firm specializing in the oncology market, including as its Chief Financial Officer and Chief Operating Officer. Also, Mr. O Boyle held various positions during his seven years with Albert Fisher North America, Inc., a publicly traded international food company, including Chief Financial Officer and Senior Vice President of Operations. Mr. O Boyle is a CPA and received a B.S. in Accounting from the Rochester Institute of Technology and successfully completed the Executive Management Program at the University of California at Los Angeles, John E. Anderson Graduate Business School. We believe Mr. O Boyle is qualified to serve on our board of directors and serve as chair of our audit committee based on his executive experience in the medical device industry and his financial and accounting expertise as described above.

Board Composition

Our certificate of incorporation and bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors. We currently have four members serving on our board of directors. In accordance with our certificate of incorporation and bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2011, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

Director	Class	Expiration of Term
Daryl J. Faulkner	Class I Director	2011 Annual Meeting
Kevin C. O Boyle	Class II Director	2012 Annual Meeting
Jon Faiz Kayyem, Ph.D.	Class III Director	2013 Annual Meeting
Christopher Gleeson	Class III Director	2013 Annual Meeting

Committees of the Board of Directors/Corporate Governance

The committees of our board of directors consist of an audit committee, a compensation committee and a corporate governance and nominating committee. Each of these committees will have the responsibilities described below upon our adoption of charters for these committees. Our board of directors may also establish other committees from time to time to assist in the discharge of its responsibilities.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting. Among other things, our audit committee determines the engagement of and approves fees paid to our independent registered public accounting firm; monitors the qualifications, independence activities and performance of our independent registered public accounting firm; approves the retention of our independent registered public accounting firm to perform any proposed and permissible non-audit services; reviews our financial statements and critical accounting estimates; and discusses with management and our independent registered public accounting firm the results of the annual audit. Our audit committee also reviews the effectiveness of internal controls and the adequacy of our disclosure controls and procedures. In addition, our audit committee maintains procedures for the receipt of employee complaints and submissions of concerns regarding accounting or auditing matters. The members of our audit committee are currently Christopher Gleeson, Daryl J. Faulkner and Kevin O Boyle. Each member currently meets the audit committee qualification and independence standards under current SEC and NASDAQ requirements.

Table of Contents

Mr. O'Boyle serves as Chairman of the audit committee and meets the requirements of an audit committee financial expert under current SEC and NASDAQ requirements based on his executive experience and education discussed in Management Directors and Officers. The meeting schedule for the audit committee has not yet been established, but we expect that the committee will meet no less frequently than quarterly. In 2009, Osmetech's audit committee held two meetings.

Compensation Committee

Our compensation committee establishes, amends, reviews and approves the compensation and benefit plans with respect to senior management and employees, including determining individual elements of total compensation of the Chief Executive Officer and other members of senior management, and reviews our performance and the performance of our executive officers with respect to these elements of compensation. Our compensation committee also determines annual retainer, meeting fees, equity awards and other compensation for members of the board of directors and administers the issuance of stock options and other awards under our stock incentive plans. The members of the compensation committee are Christopher Gleeson, Daryl J. Faulkner and Kevin O'Boyle. Each member of our compensation committee currently meets the standards for independence under the applicable NASDAQ requirements. Mr. Gleeson serves as Chairman of the compensation committee. The meeting schedule for the compensation committee has not yet been established, but we expect that the committee will meet at least once a year. In 2009, Osmetech's compensation committee held two meetings.

Our compensation committee reviews and evaluates potential risks related to our compensation policies and practices for employees and has determined that we have no compensation risks that are reasonably likely to have a material adverse effect on our company. We structure our compensation to address company-wide risk. This is accomplished in part by tying compensation to corporate goals and individual performance goals. These goals can be adjusted annually to address risks identified in the annual risk assessment. We also use a mix of different compensation elements to balance short-term awards versus long-term awards to align compensation with our business strategy and stockholders interests. We believe the combination of base salary, performance-based cash awards and stock-based incentive awards with four-year vesting periods is balanced and serves to motivate our employees to accomplish our business plan without creating risks that are reasonably likely to have a material adverse effect on our company.

Corporate Governance and Nominating Committee

Our corporate governance and nominating committee recommends the director nominees for each annual general meeting and ensures that the audit, compensation and corporate governance committees of our board of directors have the benefit of qualified and experienced independent directors. The members of our corporate governance and nominating committee are Christopher Gleeson, Daryl J. Faulkner and Kevin O'Boyle. Each member of our corporate governance and nominating committee currently meets the standards for independence under the applicable NASDAQ requirements. Mr. Faulkner serves as Chairman of the corporate governance and nominating committee. The meeting schedule for the corporate governance and nominating committee has not yet been established, but we expect that the committee will meet at least once a year. Osmetech did not have a corporate governance and nominating committee in 2009.

Code of Ethics

We have adopted a code of ethics that applies to all of our officers, including those officers responsible for financial reporting, directors and employees prior to consummation of this offering. We will post a copy of our code of ethics, and intend to post amendments to this code, or any waivers of its requirements, on our website at www.genmarkdx.com as permitted under SEC rules and regulations.

Table of Contents

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has at any time been an employee of GenMark or Osmetech. None of our executive officers serves, or has served during the last fiscal year, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of the board of directors or compensation committee of GenMark or Osmetech.

Director Independence

Our board of directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our board has determined that the following directors are independent directors as defined by the applicable rules and regulations of the NASDAQ Global Market: Christopher Gleeson, Daryl J. Faulkner and Kevin O Boyle.

Table of Contents

EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

Fiscal years 2009 and 2010 are transitional years for us as we were, and continue to be, preparing for our initial public offering. We are currently focusing on raising funds to support our operations, implementing our new sales and product development strategy, and streamlining and rebranding our operations. We have also recently strengthened our board and management team and implemented additional financial and corporate governance controls as we are preparing to transition to a U.S. public company. Our compensation program and practices evolved as part of this transition as well. As a result, the following discussion provides information regarding the current compensation program of Osmetech and its subsidiaries when referring to historical practices, and the compensation practices of GenMark when referring to our present compensation practices or those in the future. For purposes of Executive Compensation, Osmetech refers to Osmetech and its wholly owned subsidiaries.

The compensation committee of our board of directors oversees our executive compensation program. In this role, the compensation committee reviews and approves annually all compensation decisions relating to our executives, including our named executive officers.

Our compensation program is designed to attract and retain talented employees, to motivate them to achieve our key financial, operational and strategic goals and to reward them for superior performance. We believe that attracting and retaining high caliber employees and providing them with appropriate performance incentives are critical steps to helping us achieve our corporate goals and build long-term value for our stockholders.

Overview of Compensation Program

The elements of our compensation program are directed toward providing our executives with both short-term and long-term performance incentives, with the overall objective to motivate our executives to help us achieve our corporate goals and build long-term value for our stockholders. The elements of our compensation program include:

base salary;

annual performance-based cash bonus awards; and

long-term stock-based incentive awards.

We also provide our executives with insurance and a limited number of additional benefits that are typical for companies in our industry. Each of these compensation elements is described in more detail below.

In determining the relevant amounts for each of these compensation elements to be awarded to our executives, our compensation committee considers the following objectives:

A Substantial Portion of Executive Compensation Should Be Performance-Based. We believe that a substantial portion of the compensation received by each of our executives should be directly tied to, and contingent upon, the performance of our company as a whole and the executive's individual contribution and performance. To support this objective, our compensation committee established an Annual Bonus Incentive Plan, or the Bonus Plan, in 2010. The Bonus Plan is designed to align each executive's efforts with our key financial, operational and strategic goals by providing an opportunity for the executive to earn an annual cash bonus with amounts determined by considering our success in achieving our corporate goals and the executive's success in achieving individual performance goals. The performance-based cash bonus awards payable to our executive officers are based almost

Table of Contents

entirely on our success in achieving our corporate goals, which include revenue targets, new customer acquisition targets and new product development targets.

Stock-Based Incentive Awards Should Comprise a Substantial Portion of Executive Compensation. We believe that a substantial portion of executive compensation should be delivered in the form of stock-based incentive awards in order to align the long-term interests of our executives with those of our stockholders and to provide a retention incentive to our executives.

Our Executive Compensation Should Be Competitive and Fair. In order to help us attract and retain talented executives, we believe that our compensation programs should be competitive when compared to our peers as well as perceived as fair, when considered both externally as well as internally.

Compensation Process

Our compensation committee is responsible for establishing our compensation philosophy and setting the compensation levels for our executives, including base salaries, target performance-based cash bonus awards and stock-based incentive awards. The compensation committee is responsible for approving the corporate goals and individual performance goals for each of our executive officers for purposes of the performance-based cash bonus awards. To assist the compensation committee, our Chief Executive Officer will prepare a report at the beginning of each fiscal year recommending base salaries, stock-based incentive awards, corporate goals for the fiscal year and individual performance goals for each executive officer. In addition to this report, our compensation committee considers relevant market compensation data. The compensation committee in its sole discretion may accept or adjust the compensation recommendations it is provided. No executive officer is allowed to be present at the time his or her compensation is being discussed or determined by the compensation committee.

After the end of each fiscal year, our compensation committee also determines the performance-based cash bonus awards our executive officers should be paid for the prior fiscal year. In making this determination, our compensation committee evaluates our success in achieving our revenue targets and our corporate goals. To assist in this process, our Chief Executive Officer will prepare a report for the compensation committee regarding the achievement of our revenue targets and corporate goals. Based on this information, our compensation committee determines what percentage of the individual cash bonus targets each of our executive officers should receive for the past fiscal year.

Determination of Executive Compensation

In setting the compensation for our executive officers, our compensation committee places significant emphasis on the recommendation of our Chief Executive Officer (other than with respect to determining his own compensation), considers our overall performance during the prior fiscal year and the executive's individual contributions during the prior fiscal year, as well as considers relevant market data. With respect to new hires, the compensation committee considers an executive's background and historical compensation in lieu of prior year performance. For 2010, we reviewed an analysis of competitive market data for our compensation committee using the SIRS Benchmark Study, 2008, prepared by ORC Worldwide Compensation Survey, or SIRS. SIRS provides executive compensation data for companies in the medical device and diagnostic industries. We used this market data as one component of determining executive compensation in 2010.

Components of Executive Compensation

As indicated above, we compensate our executives through a combination of short-term and long-term incentives that are designed to motivate our executives to help us achieve our key financial, operational and strategic goals and build long-term value for our stockholders.

Table of Contents

Base Salary. We provide our executive officers with a base salary to compensate them for services provided to us during the fiscal year. In setting base salaries for our executive officers, our compensation committee considers the executive's position, our success in achieving our prior year corporate goals, the individual's contribution and performance during the prior fiscal year and relevant market data. The compensation committee also considers the evaluations and recommendations proposed by our Chief Executive Officer. With respect to new hires, the compensation committee considers an executive's background and historical compensation in lieu of prior year performance. The compensation committee evaluates and sets the base salaries for our executives on an annual basis following annual performance reviews, as well as upon a promotion or other change in responsibility.

In setting the base salaries for our executives for 2010, our compensation committee considered various factors including the executive's position, our success in achieving our corporate goals during 2009, the individual performance and contribution of the executive during fiscal year 2009 and the evaluations and recommendations proposed by our Chief Executive Officer. It also reviewed the market survey data provided by SIRS to ensure that the base salaries were consistent with market data. In the event of an inconsistency between the market data and the various factors used by the compensation committee to determine executive compensation, the compensation committee may make necessary upward or downward adjustments after analyzing the market data. In setting base salaries for 2010, the compensation committee did not identify any inconsistencies. Based on the compensation committee's analysis of these components, the compensation committee determines the base salaries of its executives. Based on the determinations made by our compensation committee, base salaries for our executive officers in 2010 are between the 25th and 75th percentiles as compared to our competitor companies in the medical device and diagnostics industries.

Our executive officers will be paid the following annualized base salaries for the year ending December 31, 2010:

Name and Title	Base Salary
Jon Faiz Kayyem, Ph.D., <i>Chief Executive Officer</i>	\$ 275,000
Steven Kemper, <i>Senior Vice President, Finance</i>	230,000
Pankaj Singhal, Ph.D., <i>Senior Vice President Product Development and Manufacturing</i>	220,000
John Bellano, <i>Senior Vice President, Commercial Operations</i>	200,000

Performance-Based Cash Bonus Awards. We have established a Bonus Plan for our executive officers. The Bonus Plan is designed to align each executive's efforts with our financial, operational and strategic goals by providing an opportunity for the executive to earn an annual cash bonus with amounts determined by overall achievement of our revenue targets and our corporate goals. Our compensation committee will be responsible for administering the Bonus Plan. All executives will be eligible to participate in the Bonus Plan.

Our compensation committee will be responsible for setting the target bonus amounts for our executives, and approving the overall target bonus amounts that are available under the Bonus Plan. The target bonus amounts for each executive will generally be set at a percentage of his or her base salary. Executives will not become eligible for bonus payments unless we achieve certain revenue targets. If we achieve our revenue targets, the bonuses will become payable based on a weighted percentage in accordance with achievement of our corporate goals. For 2010, our corporate goals include sales targets (40%), product development milestones (40%) and achievement of our projected gross margin (20%).

After the end of each fiscal year, the compensation committee will be responsible for setting the actual bonus amounts to be awarded. To assist our compensation committee, each year our Chief Executive

Table of Contents

Officer will provide the compensation committee with documentation regarding full or partial achievement of our revenue targets and each corporate goal.

The weighted average of each corporate goal will be multiplied by the executive's target bonus amount to determine the actual bonus amount paid in respect of each corporate goal. Actual amounts payable range from 0% to 150% of the target amounts, based upon achievement of our revenue target and our corporate goals. Total bonus is determined by adding up the sum of the weighted averages multiplied by the executive's target bonus. To reward exceptional performance in certain circumstances, the compensation committee may determine that a supplemental bonus in excess of the target bonus is appropriate and justified. However, individual incentive payments will not be an entitlement. We may terminate the Bonus Plan at any time, and may alter the terms and conditions under which the bonus awards are set, calculated or paid. The following sets forth the anticipated target bonus amounts for 2010:

Executive Officer	Bonus %	Amount at Target
Jon Faiz Kayyem, Ph.D.	75%	\$ 206,250
Steven Kemper	30%	69,000
John Bellano	50%	100,000
Pankaj Singhal, Ph.D.	30%	66,000

Stock-Based Incentive Awards. In addition to our performance-based cash bonus awards, we provide long-term stock-based incentive awards to our executive officers. These stock-based incentive awards generally consist of options to purchase shares of our common stock. We believe that stock option awards help further our compensation objectives by encouraging our executives to remain with us through at least the vesting period for these awards and providing them with an incentive to continue to focus on our long-term financial performance and increasing stockholder value.

Our executive officers receive a stock option award in connection with their initial hire, following promotions and on an annual basis. To assist the compensation committee, we have developed guidelines for initial and annual stock option awards. The guidelines for initial grants are based on the executive's position and the guidelines for annual grants are generally designed to replace the number of options initially granted to the executive at hiring that vest after one year, which is typically 25% of the initial grant award for the executive. With respect to new hires, we also considered the executive's background and historical compensation when determining the number of options to grant to the executive. The actual number of options for an executive may be higher or lower than these guidelines, based on their individual performance or extraordinary achievements. See 2010 Equity Incentive Award Plan below for additional information.

Stock and Option Grant Practices. Our compensation committee adopted a policy by which all stock and option awards to new and current employees, including our executive officers, are granted at pre-determined meeting dates of the compensation committee. Our compensation committee grants the equity awards in accordance with the dates fixed by this policy whether or not we are aware of any material non-public information (whether positive or negative) at the time of grant. Because the equity awards typically do not vest or have any realizable value for at least 12 months, we do not believe it is important whether we are aware of any material non-public information on the date of grant. The amount of realizable value related to such awards will be determined by our stock price on the date the awards vest and therefore will be determined by our financial performance in the time prior to vesting. Whether the stock price moves up or down shortly after the grant date is largely irrelevant for purposes of the equity awards.

In connection with the Reorganization and this offering, each holder of an option to purchase ordinary shares of Osmetech will hold options issued pursuant to the 2010 Plan to purchase GenMark common

Table of Contents

stock. The new GenMark options will be exercisable for that number of shares of common stock and at an exercise price per share that reflects the exchange ratio in the Reorganization. All vesting will remain unchanged.

The exercise price of any option grant is determined by reference to the fair market value of such shares, which the 2010 Plan defines as the daily volume-weighted average price of our common stock on the NASDAQ Global Market on the date of grant. Prior to completing our initial public offering, the exercise price for a share option of Osmetech was determined by converting the current quoted price on the London Stock Exchange's AIM system, into U.S. dollars based on that day's exchange rate. However, because options granted both before and after the completion of our initial public offering have been granted at fair market value, such options only have cash value to the holder to the extent that the stock price of our common stock increases during the term of the option. Our option grants generally vest 25% one year from the date of the grant, with the remaining 75% of the options vesting in equal monthly installments over the subsequent thirty-six month period.

Other Benefits

In order to attract, retain and pay market levels of compensation, we provide our executives with the following benefits:

Health Insurance. We provide each of our executives and their spouses and children the same health, dental and vision insurance coverage we make available to our other eligible employees.

Life and Disability Insurance. We provide each of our executives with the same disability and life insurance as we make available to our other eligible employees.

Pension Benefits. We do not provide pension arrangements or post-retirement health coverage for our executives or employees. Our executives and other eligible employees are eligible to participate in our 401(k) defined contribution plan. We do not currently make matching contributions to participants in the 401(k) plan, however we have previously made matching contributions, and we may opt to do so again in the future.

Nonqualified Deferred Compensation. We do not provide any nonqualified defined contribution or other deferred compensation plans to any of our employees.

Perquisites. We limit the perquisites that we make available to our executive officers. Our executives are entitled to relocation expenses on their initial hire and other benefits with de minimis value that are not otherwise available to all of our employees.

Employment Agreements

Jon Faiz Kayyem, Ph.D.

We entered into an employment agreement, effective January 1, 2010, with Dr. Kayyem, pursuant to which he has agreed to serve as our Chief Executive Officer. Dr. Kayyem's agreement provides for, among other things: (i) an annual base salary of \$275,000, subject to annual review, (ii) eligibility to participate in the Bonus Plan of up to 75% variable pay based on his current base salary, and (iii) an initial award of 248,568 options to purchase shares of our common stock.

Steven Kemper

We entered into an employment agreement, effective November 30, 2009, with Mr. Kemper, pursuant to which Mr. Kemper has agreed to serve as our Senior Vice President of Finance. Mr. Kemper's agreement provides for, among other things: (i) an annual base salary of \$230,000, subject to annual review, (ii) eligibility to participate in the Bonus Plan of up to 30% variable pay based on his current base salary, and (iii) an initial award of 85,224 options to purchase shares of our common stock. In addition, in the

Table of Contents

event of a change of control transaction, all of Mr. Kemper's then unvested option shares will automatically accelerate and vest in full. The employment agreement also provides that if Mr. Kemper's employment is terminated by us without cause or by Mr. Kemper for good reason, we will pay Mr. Kemper severance equal to: (i) six months of his base salary, or in the event his employment agreement is terminated in connection with a change of control transaction, 12 months base salary, (ii) any earned, but not yet paid, bonus amounts, (iii) continuation in our medical and dental insurance plans for six months, or in the event his employment agreement is terminated in connection with a change of control transaction, continuation in such plans for 12 months, (iv) accrued and unpaid vacation, and (v) unreimbursed expenses.

Pankaj Singhal, Ph.D.

We entered into an employment agreement, effective January 1, 2010, with Dr. Singhal, pursuant to which Dr. Singhal has agreed to serve as our Senior Vice President of Product Development and Manufacturing. Dr. Singhal's agreement provides for, among other things: (i) an annual base salary of \$220,000, subject to annual review, (ii) eligibility to participate in the Bonus Plan of up to 30% variable pay based on his current base salary, and (iii) an initial award of 85,224 options to purchase shares of our common stock.

John Bellano

We entered into an employment agreement, effective March 1, 2010, with Mr. Bellano, pursuant to which Mr. Bellano has agreed to serve as our Senior Vice President of Commercial Operations. Mr. Bellano's agreement provides for, among other things: (i) an annual base salary of \$200,000, subject to annual review, (ii) eligibility to participate in the Bonus Plan of up to 50% variable pay based on his current base salary, (iii) a guaranteed aggregate bonus of \$25,000 in the first two quarters of 2010, (iv) an initial award of 85,224 options to purchase shares of our common stock, and (v) reimbursement of relocation costs in the amount of \$130,000.

Separation Agreements

James White

We entered into a compromise agreement, effective August 10, 2009, with Mr. White, pursuant to which Mr. White resigned as Osmetech's Chief Executive Officer effective as of August 7, 2009. Pursuant to the terms of the agreement, we paid Mr. White, among other things: (i) severance payments in the amount of \$481,601, and (ii) a pension payment in the amount of \$39,132. In addition, we agreed to continue payment of Mr. White's (i) COBRA premiums until August 7, 2010, and (ii) long term and short term disability and group life insurance until August 7, 2010.

David Sandilands

We entered into a compromise agreement, effective March 19, 2010, with Mr. Sandilands, pursuant to which Mr. Sandilands resigned as Osmetech's Chief Financial Officer. Pursuant to the terms of the agreement, we paid Mr. Sandilands, among other things, (i) accrued salary and benefits through his date of resignation, (ii) accrued vacation, (iii) accrued but unpaid bonus, (iv) a termination payment in the amount of \$236,835, and (v) a pension payment in the amount of \$32,507. In addition, we have amended his grant of options made on December 23, 2009 to purchase 71,020 shares of our common stock such that they vest in full upon the listing of our common stock on the NASDAQ Global Market and remain exercisable for a period of 12 months following his termination, subject to his continuing assistance during the period prior to our initial listing on NASDAQ.

Table of Contents

2010 Equity Incentive Award Plan

GenMark Diagnostics, Inc. has adopted the 2010 Plan. We reserved 2,000,000 shares of common stock under our 2010 Plan, including the 963,514 shares underlying outstanding options after giving effect to the adjustment to the outstanding options immediately following the Reorganization and this offering based on Osmetech's options outstanding as of March 31, 2010. The 2010 Plan also contains an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2010 Plan commencing on the first January 1 after the completion of this offering and on each January 1 thereafter during the ten-year term of the 2010 Plan. The annual increase in the number of shares shall be equal to the least of:

3% of our outstanding common stock on the applicable January 1; and

a lesser number of shares as determined by our board of directors.

The material terms of the 2010 Plan are summarized below.

Administration

The compensation committee of our board of directors will administer the 2010 Plan. Following the completion of this offering, to administer the 2010 Plan, our compensation committee must consist solely of at least two members of our board of directors, each of whom is a non-employee director for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended, an outside director for purposes of Section 162(m). Subject to the terms and conditions of the 2010 Plan, our compensation committee will have the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, the number of awards to grant, the number of shares to be subject to such awards, and the terms and conditions of such awards, and to make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2010 Plan. Our compensation committee will also be authorized to establish, adopt, amend or revise rules relating to administration of the 2010 Plan. Our board of directors may at any time revert in itself the authority to administer the 2010 Plan.

Eligibility

Options, stock appreciation rights, or SARs, restricted stock and other awards under the 2010 Plan may be granted to individuals who are then our officers or employees or are the officers or employees of any of our subsidiaries. Such awards may also be granted to our non-employee directors and consultants but only employees may be granted incentive stock options, or ISOs.

Awards

The 2010 Plan will provide that our compensation committee may grant or issue stock options, SARs, restricted stock, restricted stock units, dividend equivalents, performance share awards, performance stock units, stock payments, deferred stock, performance bonus awards, performance-based awards, and other stock-based awards, or any combination thereof. Our compensation committee will consider each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonqualified stock options, or NQSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than the fair market value of a share of common stock on the date of grant, and usually will become exercisable (at the discretion of our compensation committee) in one or more installments after the grant date,

Table of Contents

subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee. NQSOs may be granted for any term specified by our compensation committee.

Incentive stock options, or ISOs, will be designed to comply with the provisions of the Internal Revenue Code and will be subject to specified restrictions contained in the Internal Revenue Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee's termination of employment, and must be exercised within the ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock, the 2010 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire upon the fifth anniversary of the date of its grant.

Restricted stock may be granted to participants and made subject to such restrictions as may be determined by our compensation committee. Typically, restricted stock may be forfeited for no consideration if the conditions or restrictions are not met, and they may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Recipients of restricted stock, unlike recipients of options, may have voting rights and may receive dividends, if any, prior to the time when the restrictions lapse.

Restricted stock units may be awarded to participants, typically without payment of consideration or for a nominal purchase price, but subject to vesting conditions including continued employment or on performance criteria established by our compensation committee. Like restricted stock, restricted stock units may not be sold or otherwise transferred or hypothecated until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.

SARs granted under the 2010 Plan typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the SAR. Our compensation committee may elect to pay SARs in cash or in common stock or in a combination of both.

Dividend equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the stock options, SARs or other awards held by the participant.

Performance bonus awards may be granted by our compensation committee on an individual or group basis. Generally, these awards will be based upon the attainment of specific performance goals that are established by our compensation committee and relate to one or more performance criteria on a specified date or dates determined by our compensation committee. Any such cash bonus paid to a covered employee within the meaning of Section 162(m) of the Internal Revenue Code may be, but need not be, qualified performance-based compensation as described below and will be paid in cash.

Stock payments may be authorized by our compensation committee in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation arrangement, made in lieu of all or any part of compensation, including bonuses, that would otherwise be payable to employees, consultants or members of our board of directors.

Table of Contents

Qualified Performance-Based Compensation

Our compensation committee may grant awards to employees who are or may be covered employees, as defined in Section 162(m) of the Internal Revenue Code, that are intended to be qualified performance-based compensation within the meaning of Section 162(m) of the Internal Revenue Code in order to preserve the deductibility of these awards for federal income tax purposes. Participants are only entitled to receive payment for qualified performance-based compensation for any given performance period to the extent that pre-established performance goals set by the plan administrator for the period are satisfied. These pre-established performance goals must be based on one or more of the following performance criteria: revenue; sales; expenses; operating income; gross margin; operating margin; earnings before any one or more of: stock-based compensation expense, interest, taxes, depreciation and amortization; pre-tax profit; net operating income; net income; economic value added; free cash flow; operating cash flow; balance of cash, cash equivalents and marketable securities; stock price; earnings per share; return on stockholder equity; return on capital; return on assets; return on investment; total stockholder return; employee satisfaction; employee retention; market share; customer satisfaction; product development; research and development expenses; completion of an identified special project; and completion of a joint venture or other corporate transaction. These performance criteria may be measured in absolute terms or as an increase or decrease in a value or a value determined relative to an index, budget or other standard selected by our compensation committee. With regard to a particular performance period, our compensation committee will have the discretion to select the length of the performance period, the type of performance-based awards to be granted, and the goals that will be used to measure the performance for the period. In determining the actual size of an individual performance-based award for a performance period, the plan administrator may reduce or eliminate (but not increase) the award. Generally, a participant will have to be employed by us throughout the performance period to be eligible for a performance-based award for any period.

Corporate Transactions

In the event of a change in control, as defined in the 2010 Plan, the compensation committee may provide for the following: accelerated vesting, assumption, continuation, substitution or the cash-out of awards.

Amendment and Termination of the 2010 Plan

Our board of directors or our compensation committee may terminate, amend or modify the 2010 Plan. However, stockholder approval of any amendment to the 2010 Plan will be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2010 Plan that increases the number of shares available under the 2010 Plan. If not terminated earlier by our compensation committee or our board of directors, the 2010 Plan will terminate on the tenth anniversary of the date of its initial approval by our board of directors.

Limitation of Directors and Officers Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to specified conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law.

We have obtained director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us. Our certificate of incorporation and bylaws also provide that we will indemnify and advance expenses to any of our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature. We will repay certain expenses incurred by a director or officer in connection with any civil, criminal, administrative or investigative action or proceeding, including actions by us or in our name. Such indemnifiable expenses include, to the maximum extent permitted by law, attorney's fees,

Table of Contents

judgments, fines, settlement amounts and other expenses reasonably incurred in connection with legal proceedings. A director or officer will not receive indemnification if he or she is found not to have acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interest.

We intend to enter into agreements to indemnify our directors and officers. These agreements provide that we will, among other things, indemnify and advance expenses to our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any such person in any action or proceeding, including any action by us arising out of such person's services as our director or officer, or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers.

Such limitation of liability and indemnification does not affect the availability of equitable remedies. In addition, we have been advised that in the opinion of the Securities and Exchange Commission, indemnification for liabilities arising under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Summary Compensation Table

The following table presents compensation information for 2009 provided by Osmetech to our former principal executive officer, our principal executive officer, our former principal financial officer and our three other most highly compensated persons serving as executive officers of Osmetech as of December 31, 2009. We refer to these executive officers as our named executive officers.

Name & Principal Position	Year	Salary ⁽¹⁾	Option Awards ⁽²⁾	All Other Compensation ⁽³⁾	Total
James White, <i>Former Chief Executive Officer</i> ⁽⁴⁾	2009	\$ 131,054	\$	\$ 520,733	\$ 651,787
Jon Faiz Kayyem, Ph.D., <i>Chief Executive Officer</i> ⁽⁵⁾	2009	69,231	936,547		1,005,778
David Sandilands, <i>Chief Financial Officer</i> ⁽⁶⁾	2009	216,712	165,749	53,409	435,870
Steven Kemper, <i>Senior Vice President, Finance</i> ⁽⁷⁾	2009	13,269	321,102		334,371
Pankaj Singhal, Ph.D., <i>Senior Vice President Product Development and Manufacturing</i> ⁽⁸⁾	2009	220,000	321,102	6,600	547,702
John Bellano, <i>Senior Vice President, Commercial Operations</i> ⁽⁹⁾	2009	7,692	321,102		328,794

⁽¹⁾Mr. Sandilands and Mr. White's salaries and all other compensation are denominated in British pounds and were converted to U.S. dollars at the rate of 1.558 U.S. dollars to one British pound, which was an average of the month-end exchange rates for 2009.

⁽²⁾Figures reflected are based on the grant date fair value of all awards made during the year calculated using the assumptions described in note 4 to Osmetech's audited financial statements included elsewhere in this prospectus, disregarding estimated forfeitures. The stock option awards are denominated in British pounds and were converted to U.S. dollars at the rate of 1.6167 U.S. dollars to one British pound, which was the exchange rate on December 31, 2009.

⁽³⁾Mr. White's all other compensation consists of \$473,351 severance, \$8,250 healthcare benefits and \$39,132 of pension costs. Mr. Sandilands' all other compensation consists of \$32,507 of pension costs, \$11,685 car allowance and a \$9,217 payment in lieu of healthcare benefits.

Table of Contents

(4) Mr. White resigned as Chief Executive Officer of Osmetech in August 2009.

(5) Dr. Kayyem was appointed Chief Executive Officer of Osmetech in August 2009 and President and Chief Executive Officer of GenMark in March 2010.

(6) Mr. Sandilands resigned as Chief Financial Officer of Osmetech in March 2010.

(7) Mr. Kemper was appointed Senior Vice President, Finance of Osmetech in November 2009 and Chief Financial Officer of GenMark in March 2010.

(8) Dr. Singhal was appointed Senior Vice President, Product Development and Manufacturing of GenMark in March 2010. Dr. Singhal served as Chief Operating Officer of Osmetech during all of 2009. Dr. Singhal's all other compensation consists of matching 401(k) contributions by Osmetech.

(9) Mr. Bellano was appointed Senior Vice President, Commercial Operations of Osmetech in December 2009 and Senior Vice President, Commercial Operations of GenMark in March 2010.

Grants of Plan-Based Awards in 2009

The following table sets forth information regarding grants of awards made to our named executive officers during the fiscal year ended December 31, 2009.

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards (\$/Share)	Grant Date Fair Value of Stock Option Awards/ Incremental Fair Value(\$) ⁽⁷⁾
James White, <i>Former Chief Executive Officer</i> ⁽¹⁾				
Jon Faiz Kayyem, Ph.D., <i>Chief Executive Officer</i> ⁽²⁾	12/23/2009	248,568	7.25	936,547
David Sandilands, <i>Chief Financial Officer</i> ⁽³⁾	12/23/2009	71,020	7.25	165,749
Steven Kemper, <i>Senior Vice President, Finance</i> ⁽⁴⁾	12/23/2009	85,224	7.25	321,102
Pankaj Singhal, Ph.D., <i>Senior Vice President Product Development and Manufacturing</i> ⁽⁵⁾	12/23/2009	85,224	7.25	321,102
John Bellano, <i>Senior Vice President, Commercial Operations</i> ⁽⁶⁾	12/23/2009	85,224	7.25	321,102

(1) Mr. White resigned as Chief Executive Officer of Osmetech in August 2009.

(2) Dr. Kayyem was appointed Chief Executive Officer of Osmetech in August 2009 and President and Chief Executive Officer of GenMark in March 2010.

(3) Mr. Sandilands resigned as Chief Financial Officer of Osmetech in March 2010.

(4) Mr. Kemper was appointed Senior Vice President, Finance of Osmetech in November 2009 and Chief Financial Officer of GenMark in March 2010.

(5) Dr. Singhal was appointed Senior Vice President, Product Development and Manufacturing of GenMark in March 2010. Dr. Singhal served as Chief Operating Officer of Osmetech during all of 2009.

(6) Mr. Bellano was appointed Senior Vice President, Commercial Operations of Osmetech in December 2009 and Senior Vice President, Commercial Operations of GenMark in March 2010.

(7) Stock option awards were granted at 4.485 British pounds (\$7.25) which were converted to U.S. dollars using an exchange rate of 1.6167 U.S. dollars to one British pound, which was the exchange rate on December 31, 2009.

Table of Contents**Outstanding Option Awards at Year End**

The following table sets forth information regarding outstanding option awards held by our named executive officers at December 31, 2009.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (\$/Share)	Option Expiration Date
James White,	9,002		0.37 ⁽⁷⁾	12/31/10
<i>Former Chief Executive Officer</i> ⁽¹⁾	2,148		0.37 ⁽⁷⁾	1/10/10
Jon Faiz Kayyem, Ph.D.,		248,568	7.25 ⁽⁸⁾	12/23/19
<i>Chief Executive Officer</i> ^{(2) (9)}				
David Sandilands,	6,072		0.37 ⁽⁷⁾	3/19/11
<i>Chief Financial Officer</i> ⁽³⁾		71,020	7.25 ⁽⁸⁾	3/19/11
Steven Kemper,		85,224	7.25 ⁽⁸⁾	12/23/19
<i>Senior Vice President, Finance</i> ^{(4) (9)}				
Pankaj Singhal, Ph.D.,	19,530	65,694	7.25 ⁽⁸⁾	12/23/19
<i>Senior Vice President Product Development and Manufacturing</i> ^{(5) (10)}				
John Bellano,		85,224	7.25 ⁽⁸⁾	12/23/19
<i>Senior Vice President, Commercial Operations</i> ^{(6) (9)}				

⁽¹⁾ Mr. White resigned as Chief Executive Officer of Osmetech in August 2009.

⁽²⁾ Dr. Kayyem was appointed Chief Executive Officer of Osmetech in August 2009 and President and Chief Executive Officer of GenMark in March 2010.

⁽³⁾ Mr. Sandilands resigned as Chief Financial Officer of Osmetech in March 2010. Mr. Sandilands' options vest in full upon the listing of our common stock on the NASDAQ Global Market and remain exercisable for a period of 12 months following his termination.

⁽⁴⁾ Mr. Kemper was appointed Senior Vice President, Finance of Osmetech in November 2009 and Chief Financial Officer of GenMark in March 2010.

⁽⁵⁾ Dr. Singhal was appointed Senior Vice President, Product Development and Manufacturing of GenMark in March 2010. Dr. Singhal served as Chief Operating Officer of Osmetech during all of 2009.

⁽⁶⁾ Mr. Bellano was appointed Senior Vice President, Commercial Operations of Osmetech in December 2009 and Senior Vice President, Commercial Operations of GenMark in March 2010.

⁽⁷⁾ Stock option awards were granted at 0.23 British pounds (\$0.37) and converted to U.S. dollars at the rate of 1.6167 U.S. dollars to one British pound.

⁽⁸⁾ Stock option awards were granted at 4.485 British pounds (\$7.25) and converted to U.S. dollars at the rate of 1.6167 U.S. dollars to one British pound.

⁽⁹⁾ Options for each executive vest 25% one year from the date of the grant with the remaining options vesting in equal monthly installments over the subsequent thirty-six month period. Vesting of all stock option awards accelerates in full upon a change of control transaction.

⁽¹⁰⁾ 19,530 options vested on the grant date with the remaining options vesting in equal monthly installments over the subsequent thirty-seven month period. Vesting of all stock option awards accelerates in full upon a change of control transaction.

Option Exercises and Stock Vested

None of our named executive officers exercised options during the fiscal year ended December 31, 2009 and we have never granted any restricted stock awards.

Table of Contents**Potential Payments upon Termination or Change in Control**

The table below describes the potential payments or benefits to our named executive officers upon a change of control and upon termination of employment without cause, as if each executive's employment terminated as of December 31, 2009, pursuant to the agreements described above in the section entitled "Executive Compensation - Employment Agreements" and "Executive Compensation - Separation Agreements."

Name	Base Salary	Pension	Health	Stock Option Vesting ⁽⁷⁾	Other	Total
James White, <i>Former Chief Executive Officer</i> ⁽¹⁾ Jon Faiz Kayyem, Ph.D., <i>Chief Executive Officer</i> ⁽²⁾ David Sandilands,	\$	\$ 39,132	\$ 19,765	\$	\$ 481,601	\$ 540,598
Steven Kemper, <i>Senior Vice President, Finance</i> ⁽⁴⁾ Pankaj Singhal, Ph.D., <i>Senior Vice President Product Development and Manufacturing</i> ⁽⁵⁾ John Bellano, <i>Senior Vice President, Commercial Operations</i> ⁽⁶⁾	237,614	32,507			93,614	363,735
	230,000		15,600			245,600

⁽¹⁾ Reflects payments made by us pursuant to the separation agreement entered into with Mr. White in August 2009, including \$481,601 of severance payments. Mr. White resigned as Chief Executive Officer of Osmetech in August 2009.

⁽²⁾ Dr. Kayyem was appointed Chief Executive Officer of Osmetech in August 2009 and President and Chief Executive Officer of GenMark in March 2010.

⁽³⁾ Mr. Sandilands resigned as Chief Financial Officer of Osmetech in March 2010 and entered into a separation agreement with us. For base salary, Mr. Sandilands is due 152,516 British pounds and for pension costs he is due 20,865 British pounds. Both were converted at an exchange rate of 1.558 U.S. dollars to one British pound, which was an average of the 12 month-end exchange rates for 2009. Other represents the Black-Scholes value of the extension of the expiration date of his option grant pursuant to his separation agreement which allows for vesting of his options for up to one year following his termination, and holiday and bonus payments.

⁽⁴⁾ Mr. Kemper was appointed Senior Vice President, Finance of Osmetech in November 2009 and Chief Financial Officer of GenMark in March 2010. Mr. Kemper is due \$230,000 of base salary and \$15,600 of health benefits upon a termination in connection with a change in control transaction and \$115,000 of base salary and \$7,800 of health benefits upon a termination by us without cause or upon a termination by Mr. Kemper for good reason.

⁽⁵⁾ Dr. Singhal was appointed Senior Vice President, Product Development and Manufacturing of GenMark in March 2010. Dr. Singhal served as Chief Operating Officer of Osmetech during all of 2009.

⁽⁶⁾ Mr. Bellano was appointed Senior Vice President, Commercial Operations of Osmetech in December 2009 and Senior Vice President, Commercial Operations of GenMark in March 2010.

⁽⁷⁾ Estimated by multiplying the number of options that vest upon change in control by the difference in fair market value on December 31, 2009 (4.31 British pounds) and the exercise price. Because the fair market value was not higher than the exercise price of all unvested options held, the amount is estimated at zero for each.

Table of Contents

Non-Employee Director Compensation Table

During 2009, certain non-employee-directors of Osmetech received compensation as described below:

Name ⁽¹⁾	Fees Earned or Paid in Cash	Option Awards ⁽²⁾	Total
Christopher Gleeson ⁽³⁾	\$ 12,500	\$ 1,126,641	\$ 1,139,141
Daryl J. Faulkner ⁽⁴⁾	15,000	122,828	137,828

⁽¹⁾Mr. O Boyle was appointed to the board of directors of GenMark in March 2010 and did not previously serve on the board of directors of Osmetech.

⁽²⁾Reflects the grant date fair value of all awards made during the year calculated using the assumptions described in note 4 to Osmetech's audited financial statements included elsewhere in this prospectus, disregarding estimated forfeitures.

⁽³⁾Mr. Gleeson was appointed to the board of directors of Osmetech in July 2009. Option awards represent warrants to purchase 220,792 shares of our common stock and options to purchase 54,979 shares of our common stock. As of December 31, 2009, Mr. Gleeson held warrants to purchase 220,792 shares of our common stock and options to purchase 54,979 shares of our common stock.

⁽⁴⁾As of December 31, 2009, Mr. Faulkner held options to purchase 30,864 shares of our common stock.

In 2009, the board of directors adopted our independent director compensation policy, pursuant to which independent directors will be compensated for their services on our board of directors. Pursuant to the policy:

each independent director will receive an annual fee of \$60,000 payable for the director's service during the year;

the Chairman of the audit committee will receive an additional annual fee of \$15,000 for the Chairman's service during the year; and

the Chairman of the Board will receive an additional annual fee of \$40,000 for the Chairman's service during the year.

The fees payable pursuant to the independent director compensation policy will be payable at the date of the annual stockholders' meeting of each year of service. The board of directors will have discretion to allocate the percent of the fees payable in cash and the percent of the fees payable in options to purchase shares of our common stock. Any options grants will have an exercise price per share determined at the fair market value on the date of grant and vest over four years, with 25% of options vesting one year from the date of the grant, and 75% of options vesting in equal monthly installments over the subsequent 36-month period. Any cash fees will be payable quarterly within thirty days of the beginning of each quarter. Each director is also entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the board of directors and any committee on which he or she serves.

In addition, we granted additional option awards to our directors in 2009.

Table of Contents**PRINCIPAL STOCKHOLDERS**

The following table presents information about the beneficial ownership of our common stock as of March 31, 2010, giving effect to the Reorganization and as adjusted to reflect the shares offered by this prospectus, by:

each existing stockholder we know to beneficially own 5% or more of our common stock, which we call our principal stockholders;

each of our directors;

each of our executive officers; and

all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days following March 31, 2010, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders.

Name of Beneficial Owner	Number of Common Shares Owned Before the Offering ⁽¹⁾	Number of Common Shares Owned After the Offering	Percentage of Shares Outstanding	
			Before Offering ⁽¹⁾	After Offering ⁽¹⁾
Principal Stockholders⁽²⁾				
Gartmore Investment Limited, et. al. ⁽³⁾	1,324,266	1,324,266	18.6%	11.3%
Efficacy Capital, Ltd. ⁽⁴⁾	877,897	877,897	12.3%	7.5%
FMR, LLC ⁽⁵⁾	711,096	711,096	10.0%	6.1%
Schroders Investment Management Ltd. ⁽⁶⁾	621,632	621,632	8.7%	5.3%
Ronin Capital L.L.C. ⁽⁷⁾	525,933	858,171	7.4%	7.3%
Directors and Executive Officers				
Jon Faiz Kayyem, Ph.D. ⁽⁸⁾	505,893	755,893	7.1%	6.4%
Christopher Gleeson ⁽⁹⁾	494,389	1,827,722	6.7%	15.3%
Pankaj Singhal, Ph.D. ⁽¹⁰⁾	28,408	28,408	*	*
Daryl J. Faulkner ⁽¹¹⁾	14,144	30,810	*	*
Kevin O Boyle			*	*
Steven Kemper			*	*
John Bellano ⁽¹²⁾		8,333	*	*
All directors and senior management as a group (7 persons)	1,042,834	2,651,166	14.1%	22.1%

* Indicates beneficial ownership of less than one percent of our shares of common stock.

⁽¹⁾ Number of shares owned as shown both in this table and the accompanying footnotes and percentage ownership before and after the offering is based on 7,123,512 shares of common stock outstanding on March 31, 2010 after giving effect to the Reorganization and assuming none of the stockholders purchase shares in the offering. The percentage ownership after the offering is based upon the 4,600,000 shares to be issued in this offering.

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

- (2) Ownership of shares held by Gartmore Investment Limited and Schroders plc is based upon ownership amounts reported to Osmetech by these principal stockholders on May 11, 2010. Ownership of shares held by Efficacy Capital, Ltd. is based upon ownership amounts reported to Osmetech by Efficacy Capital on January 19, 2010. Ownership of shares of held by Ronin Capital L.L.C. is based upon ownership amounts reported to Osmetech by Ronin Capital on March 17, 2010. Ownership of shares held by FMR, LLC is based upon ownership amounts reported to Osmetech by FMR, LLC on May 3, 2010.
- (3) The address of Gartmore Investment Limited is Gartmore House, 8 Fenchurch Place, London, EC3M 4PB, UK. 539,275 of the shares of common stock are held directly by Alphagen Volantis Fund Limited, 318,520 of the shares of common stock are held

Table of Contents

- directly by Gartmore Fund Managers Limited A/c Gartmore UK & Irish Smaller Companies, 357,899 of the shares of common stock are held directly by Strathclyde Pension Fund and 108,572 of the shares of common stock are held directly by Gartmore Growth Opportunities Plc. Gartmore Investment Limited is the investment manager for each of these funds. Gartmore Investment Limited is a wholly owned subsidiary of Gartmore Investment Management Limited, which is a wholly owned subsidiary of Gartmore Group Ltd. Voting and dispositive power over the shares resides with the board of directors of Gartmore Group Ltd. The board of directors of Gartmore Group Ltd consists of Andrew Skirton, Jeffrey Meyer, Keith Starling, Patrick Healy, Blake Kleinman, David Barclay and David Lindsell. Certain of Gartmore Investment Limited's affiliates are FINRA members, none of which are participating in this offering.
- (4) The address of Efficacy Capital, Ltd. is 11622 El Camino Real, Suite 100, San Diego, CA 92130. 864,983 of the shares of common stock are held directly by Efficacy Biotech Master Fund and 12,914 of our shares of common stock are held directly by FMG Special Opportunity Fund. Mark Lappe, the general partner of Efficacy Capital, Ltd., has voting and dispositive power with respect to the shares. Mr. Lappe disclaims beneficial ownership except to the extent of his pecuniary interest therein.
- (5) The address of FMR, LLC is 82 Devonshire Street V13H, Boston, MA 02109. 326,087 of the shares are held directly by Fidelity Select Portfolios: Medical Equipment and Systems Portfolio, 220,758 of the shares are held directly by Fidelity Select Portfolios: Health Care Portfolio, 83,125 of the shares are held directly by Fidelity Central Investment Portfolios LLC: Fidelity Health Care Central Fund, 60,090 of the shares are held directly by Fidelity Advisor Series VII: Fidelity Advisor Health Care Fund, 11,988 of the shares are held directly by Fidelity Capital Trust: Fidelity Stock Selector, and 9,048 of the shares are held directly by Variable Insurance Products Fund IV: Health Care Portfolio. Fidelity Management & Research Company (Fidelity), a wholly owned subsidiary of FMR LLC and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of these 711,096 shares, as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. Edward C. Johnson 3d, Chairman of FMR, LLC, and FMR LLC, through its control of Fidelity, and the funds each has sole power to dispose of the all shares owned by the funds. Neither FMR LLC nor Edward C. Johnson 3d has the sole power to vote or direct the voting of the shares owned directly by the funds, which power resides with the funds' Boards of Trustees. The fund's Board of Trustees consists of Edward C. Johnson 3d, James C. Curvey, Dennis J. Dirks, Alan J. Lacy, Ned C. Lautenbach, Joseph Mauriello, Cornelia M. Small, William S. Stavropoulos, David M. Thomas and Michael E. Wiley. Certain of Fidelity's affiliates are FINRA members, none of which are participating in this offering.
- (6) The address of Schroders Investment Management Ltd. is 31 Gresham Street, London, EC2V 7QA, UK. 252,969 of the shares are held directly by Schroder UK Small Companies Fund, 180,175 shares are held directly by British Coal Staff Superann Scheme, 180,017 shares are held directly by Mineworkers Pension Scheme, 5,634 shares are held directly by Arcadia Group Pension Scheme, and 2,837 shares are held directly by Arcadia Group Senior Exec PS. Schroder Investment Management Ltd. is investment manager for each of these funds. Schroders Investment Management Ltd. is a wholly owned subsidiary of Schroders plc. Voting and dispositive power over the shares resides with the board of directors of Schroders plc. The board of directors of Schroders plc consists of Michael Miles, Michael Dobson, Alan Brown, Philip Mallinckrodt, Kevin Parry, Massimo Tosato, Andrew Beeson, Luc Bertrand, Lord Howard of Penrith, Sir Peter Job, Merlyn Lowther and Bruno Schroder.
- (7) The address of Ronin Capital L.L.C. is 230 South LaSalle, Suite 400, Chicago, IL 60604. 350,245 of the shares of common stock are held directly by John Stafford III, 175,122 of our shares of common stock are held directly by Ronin Trading U.K. LLP and 566 shares are held directly by Ronin Capital L.L.C. Ronin Capital L.L.C. is the Designated Member with a controlling interest in Ronin Trading U.K. LLP. John Stafford III is the President and Chief Executive Officer of Ronin Capital L.L.C. and has voting and dispositive power with respect to the shares held by Ronin Capital L.L.C. and Ronin Trading U.K. LLP. Mr. Stafford disclaims beneficial ownership except to the extent of his pecuniary interest therein. Ronin Capital L.L.C. and its affiliated entities have committed to purchase 332,238 shares in this offering and the number of common shares owned after the offering and percentage of shares outstanding owned after the offering in the table above reflect the acquisition of beneficial ownership of that number of shares by Ronin Capital L.L.C. in this offering. Ronin Capital, LLC is a registered broker dealer and its wholly owned subsidiary DART Executions, LLC is a FINRA member.
- (8) Includes 61,651 shares of common stock held by HI Charitable Remainder Uni Trust, 124,934 shares of common stock held by The Jon Faiz Kayyem and Paige N. Gates Family Trust, dated April 1, 2000, and 319,308 shares of common stock held by IFIN LP. Dr. Kayyem is trustee of the HI Charitable Remainder Uni Trust, trustee of The Jon Faiz Kayyem and Paige N. Gates Family Trust, dated April 1, 2000, and President of In-Motion LLC, the general partner of IFIN LP. Dr. Kayyem may be deemed to have beneficial ownership of the shares held by these entities. Dr. Kayyem has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$1,500,000 in this offering. The number of common shares owned after the offering and the percentage of shares outstanding owned after the offering in the table above reflect the acquisition of beneficial ownership of 250,000 shares by IFIN LP in this offering based on Dr. Kayyem's indication of interest and the initial public offering price of \$6.00 per share.
- (9) Includes warrants to purchase 220,792 shares of common stock and options to purchase 13,180 shares of common stock which are currently exercisable or exercisable within 60 days of March 31, 2010. Also includes 229,232 shares held by the Gleeson Family Trust. Mr. Gleeson is the trustee of the Gleeson Family Trust and may be deemed to have beneficial ownership of these shares. Mr. Gleeson has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$8,000,000 in this offering. The number of common shares owned after the offering and the percentage of shares outstanding owned after the offering in the table above reflect the acquisition of beneficial ownership of 1,333,333 shares by the Gleeson Family Trust in this offering based on Mr. Gleeson's indication of interest and the initial public offering price of \$6.00 per share.
- (10) Includes options to purchase 28,408 shares which are currently exercisable or exercisable within 60 days of March 31, 2010.
- (11) Includes options to purchase 14,144 shares of common stock which are currently exercisable or exercisable within 60 days of March 31, 2010. Mr. Faulkner has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$100,000 in this offering. The number of common shares owned after the offering and the percentage of shares outstanding owned after the offering in the table above reflect the acquisition of beneficial ownership of 16,666 shares by Mr. Faulkner in this offering based on his indication of interest and the initial public offering price of \$6.00 per share.
- (12) Mr. Bellano has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$50,000 in this offering. The number of common shares owned after the offering and the percentage of shares outstanding owned after the offering in the table above reflect the acquisition of beneficial ownership of 8,333 shares by Mr. Bellano in this offering based on his indication of interest and the initial public offering price of \$6.00 per share.

Table of Contents

RELATED PARTY TRANSACTIONS

Since January 1, 2007, there have been no transactions, or currently proposed transactions, in which we were or are to be a participant involving an amount exceeding \$120,000, and in which any related person had or will have a direct or indirect material interest, except as described below.

Issuances of Ordinary Shares by Osmetech

In 2008, Osmetech completed two private financing transactions, in which it issued 1,050,813 ordinary shares at \$3.36 per share for net proceeds of approximately \$3.5 million on December 5, 2008 and 1,942,624 ordinary shares at \$3.36 per share for net proceeds of approximately \$6.5 million on December 21, 2008. Efficacy Capital Limited purchased 396,533 ordinary shares in the December 5, 2008 financing and 733,066 ordinary shares in the December 21, 2008 financing. Dr. Kayyem, our Chief Executive Officer and one of our directors, served as a managing partner of Efficacy Capital Limited at the time of these financings.

In 2009, Osmetech completed two private financing transactions, in which it issued 1,139,285 ordinary shares at \$7.59 per share for net proceeds of approximately \$8.6 million on June 25, 2009 and 2,086,090 ordinary shares at \$7.60 per share for net proceeds of approximately \$15.8 million on December 21, 2009. The securities purchased by investors in these financings included the following:

Mr. Gleeson, one of our directors, purchased 132,475 ordinary shares in the June 25, 2009 financing and 127,942 ordinary shares in the December 21, 2009 financing.

Efficacy Capital Limited purchased 33,119 ordinary shares in the June 25, 2009 financing and 31,985 ordinary shares in the December 21, 2009 financing. Dr. Kayyem, our Chief Executive Officer and one of our directors, served as a managing partner of Efficacy Capital Limited at the time of these financings.

Issuance of Shares in this Offering

Certain of our directors, officers and beneficial owners of 5% or more of our common stock have indicated an interest in purchasing shares in this offering at the price to the public to be paid by all investors in this offering as follows:

Mr. Gleeson, one of our directors, has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$8,000,000;

Dr. Kayyem, our President and Chief Executive Officer and one of our directors, has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$1,500,000;

Daryl J. Faulkner, one of our directors, has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$100,000;

John Bellano, our Senior Vice President, Commercial Operations, has indicated an interest in purchasing shares of common stock with an aggregate public offering price of up to \$50,000; and

Ronin Capital L.L.C., which beneficially owns approximately 7.4% of our common stock before this offering, has committed to purchase 332,238 shares in this offering.

Indemnification Agreements

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

We intend to enter into indemnification agreements with our directors and executive officers for the indemnification of and advancement of expenses to these persons. We also intend to enter into these agreements with our future directors and executive officers. The indemnification agreements will provide,

Table of Contents

among other things, that subject to certain procedures and conditions, we will, to the fullest extent permitted by Delaware law, indemnify the directors and officers against all liabilities and expenses, actually or reasonably incurred by a director or officer in connection with the investigation, defense, settlement or appeal of a proceeding if, by reason of the indemnitee's status as a director or officer, the indemnitee was or is a party or is threatened to be made a party to the proceeding. In addition, the indemnification agreements provide for the advancement of expenses incurred by the indemnitee, subject to certain conditions and exceptions, in connection with any proceeding covered by the indemnification agreements. The indemnification agreements also require us to maintain directors' and officers' liability insurance in a reasonable amount from established and reputable insurers.

Policy for Approval of Related Party Transactions

Pursuant to the written charter of our audit committee, the audit committee is responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our board of directors determines may be considered related parties, has or will have a direct or indirect material interest. If advanced approval is not feasible, the audit committee has the authority to ratify a related party transaction at the next audit committee meeting. For purposes of our audit committee charter, a material interest is deemed to be any consideration received by such a party in excess of \$120,000 per year.

In reviewing and approving such transactions, the audit committee shall obtain, or shall direct our management to obtain on its behalf, all information that the committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of the committee. This approval authority may also be delegated to the Chairman of the audit committee in respect of any transaction in which the expected amount is less than \$250,000. No related party transaction may be entered into prior to the completion of these procedures.

The audit committee or its Chairman, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as the committee or the Chairman determines in good faith to be necessary. These facts and circumstances will typically include, but not be limited to, the material terms of the transaction, the nature of the related party's interest in the transaction, the significance of the transaction to the related party and the nature of our relationship with the related party, the significance of the transaction to us, and whether the transaction would be likely to impair (or create an appearance of impairing) the judgment of a director or executive officer to act in our best interest. No member of the audit committee may participate in any review, consideration or approval of any related party transaction with respect to which the member or any of his or her immediate family members is the related party, except that such member of the audit committee will be required to provide all material information concerning the related party transaction to the audit committee.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

The following description of the capital stock and provisions of the certificate of incorporation and bylaws of GenMark are summaries and are qualified by reference to the certificate of incorporation and the bylaws of GenMark. Copies of these documents have been filed with the Securities and Exchange Commission as exhibits to the registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to GenMark's capital structure that will occur upon the completion of the Reorganization and this offering.

Reorganization

Immediately prior to the closing of this offering, GenMark will acquire all of the outstanding ordinary shares of Osmetech by way of a Reorganization under the applicable laws of the United Kingdom. In the Reorganization, all of the issued ordinary shares of Osmetech will be 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 will be a subsidiary controlled by GenMark, and the former shareholders of Osmetech will hold shares of GenMark. The Osmetech shareholders will receive one share of GenMark common stock for every 230 ordinary shares of Osmetech, subject to any Osmetech shareholder who is due to receive fractional shares of GenMark common stock in the Reorganization becoming entitled to receive a single share of GenMark common stock in lieu of such fractional shares.

General

Pursuant to the GenMark certificate of incorporation, GenMark is authorized to issue 100,000,000 shares of common stock, \$0.0001 par value per share, and 5,000,000 shares of preferred stock, \$0.0001 par value per share, none of which will be designated or issued upon completion of this offering. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

GenMark was formed by Osmetech in Delaware in February 2010 in order to facilitate the Reorganization and this offering. As of March 31, 2010, Osmetech held 1,000 shares of GenMark common stock, and was the sole stockholder.

As of March 31, 2010, Osmetech had 1,638,407,754 ordinary shares issued and outstanding without giving effect to the Reorganization. These shares were held by approximately 9,055 shareholders of record. Based on the number of outstanding ordinary shares of Osmetech as of March 31, 2010, and the exchange ratio set forth in the Reorganization, 7,123,512 shares of common stock of GenMark will be issued to holders of Osmetech ordinary shares.

Common Stock

GenMark will have a total of 11,723,512 shares of common stock outstanding immediately following the Reorganization and this offering, assuming:

4,600,000 shares of common stock offered by us in this offering; and

7,123,512 shares of common stock outstanding after giving effect to the Reorganization and based on the number of outstanding ordinary shares of Osmetech as of March 31, 2010.

Holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. The holders of common stock have no preferences or

Table of Contents

rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Preferred Stock

GenMark will have no shares of preferred stock outstanding immediately following the Reorganization and this offering. The GenMark board of directors has the authority, without further stockholder authorization, to issue from time to time up to 5,000,000 shares of preferred stock in one or more series and to fix the terms, limitations, voting rights, relative rights and preferences and variations of each series. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. Although we have no present plans to issue any other shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

Stock Options

GenMark reserved an aggregate of 2,000,000 shares of common stock for issuance under its 2010 Plan, which is subject to increase on an annual basis pursuant to the terms of the plan. In connection with the Reorganization and this offering, GenMark will offer each holder of an option to purchase the ordinary shares of Osmetech, the opportunity to surrender their outstanding Osmetech options in consideration for options issued pursuant to the 2010 Plan to purchase GenMark common stock. The new GenMark options will be exercisable for that number of shares of common stock and at an exercise price per share that reflects the exchange ratio in the Reorganization.

As of March 31, 2010, GenMark had outstanding options to purchase an aggregate of 963,514 shares of common stock giving effect to the adjustment to the outstanding options immediately following the Reorganization and this offering. All outstanding options following the Reorganization will be governed by the terms of the 2010 Plan. Of this aggregate amount, the GenMark options would have a weighted-average exercise price of \$7.45 per share, and options to purchase 188,587 shares would have been vested as of March 31, 2010.

Warrants

As of March 31, 2010, there were outstanding warrants to purchase 220,792 shares of GenMark common stock at a weighted-average exercise price of \$8.32 per share giving effect to the adjustment to the outstanding warrants immediately following the Reorganization.

Anti-Takeover Provisions of Delaware Law, Our Certificate of Incorporation and Our Bylaws

Provisions of the DGCL and our certificate of incorporation and by-laws could make it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and takeover bids that our board of directors may consider inadequate and to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because, among other things, negotiation of these proposals could result in an improvement of their terms.

Table of Contents

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, an anti-takeover statute. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the time the person became an interested stockholder, unless the business combination or the acquisition of shares that resulted in a stockholder becoming an interested stockholder is approved in a prescribed manner. Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns (or within three years prior to the determination of interested stockholder status did own) 15% or more of a corporation's voting stock. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Classified Board

Our certificate of incorporation and our bylaws provide that our board of directors is divided into three classes, each comprised of three directors. The director designated as a Class I director will have a term expiring at the first annual meeting of stockholders following this offering, which we expect to hold in 2011. The director designated as a Class II director will have a term expiring at the following year's annual meeting of stockholders, which we expect to hold in 2012, and the directors designated as Class III directors will have a term expiring at the following year's annual meeting of stockholders, which we expect to hold in 2013. Directors for each class will be elected at the annual meeting of stockholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election. Under the classified board provisions, it would take at least two elections of directors for any individual or group to gain control of our board. Accordingly, these provisions could discourage a third party from initiating a proxy contest, making a tender offer or otherwise attempting to gain control of us.

Removal of Directors

Our bylaws provide that our stockholders may only remove our directors with cause.

Amendment

Our certificate of incorporation and our bylaws provide that the affirmative vote of the holders of at least 80% of our voting stock then outstanding is required to amend certain provisions relating to the number, term, election and removal of our directors, the filling of our board vacancies, stockholder notice procedures, the calling of special meetings of stockholders and the indemnification of directors.

Size of Board and Vacancies

Our by-laws provide that the number of directors on our board of directors is fixed exclusively by our board of directors. Newly created directorships resulting from any increase in our authorized number of directors will be filled by a majority of our board of directors then in office, provided that a majority of the entire board of directors, or a quorum, is present and any vacancies in our board of directors resulting from death, resignation, retirement, disqualification, removal from office or other cause will be filled generally by the majority vote of our remaining directors in office, even if less than a quorum is present.

Special Stockholder Meetings

Our certificate of incorporation provides that only the Chairman of our board of directors, our Chief Executive Officer or our board of directors pursuant to a resolution adopted by a majority of the entire board of directors may call special meetings of our stockholders.

Table of Contents

Stockholder Action by Unanimous Written Consent

Our certificate of incorporation expressly eliminates the right of our stockholders to act by written consent other than by unanimous written consent. Stockholder action must take place at the annual or a special meeting of our stockholders or be effected by unanimous written consent.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our by-laws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors other than nominations made by or at the direction of our board of directors or a committee of our board of directors.

No Cumulative Voting

The DGCL provides that stockholders are denied the right to cumulate votes in the election of directors unless our certificate of incorporation provides otherwise. Our certificate of incorporation does not provide for cumulative voting.

Undesignated Preferred Stock

The authority that will be possessed by our board of directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest or otherwise by making such attempts more difficult or more costly. Our board of directors may issue preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer and Trust Company.

Stock Exchange

Our common stock is listed on the NASDAQ Global Market under the symbol GNMK.

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALES

Prior to this offering, there has been no public market for the GenMark common stock, and we can not assure you that a significant public market for the GenMark common stock will develop or be sustained after this offering. Future sales of substantial amounts of GenMark common stock, including shares of common stock issued to the former shareholders of Osmetech in connection with the Reorganization and shares of GenMark common stock issuable upon exercise of outstanding options and warrants, in the public market after this offering, or the perception that these sales could occur, could adversely affect the prevailing market price of the GenMark common stock and could impair GenMark's future ability to raise capital through the sale of equity securities.

Sale of Outstanding Shares

Based on the number of shares outstanding as of March 31, 2010 and the completion of the Reorganization, GenMark will have approximately 11,723,512 shares of common stock outstanding after the completion of this offering, and approximately 12,413,512 shares if the underwriters exercise their over-allotment option in full. Of these shares, the 4,600,000 shares of common stock sold in this offering, plus the additional shares if the underwriters exercise their over-allotment option in full, will be freely transferable without restriction, unless purchased by our affiliates, as that term is defined under Rule 144 of the Securities Act.

The remaining 7,123,512 shares of common stock to be outstanding immediately following the completion of this offering were issued to the former shareholders of Osmetech as part of the Reorganization in reliance on an exemption from the registration requirements of the Securities Act. As of the date of this prospectus, these outstanding shares will be eligible for sale as follows:

3,443,943 shares of common stock that are not held by our directors, officers and other affiliates and are not subject to the 180-day lock-up period described below will be immediately eligible for sale in the public market upon the effective date of the registration statement relating to this offering;

525,933 shares of common stock that are not held by our directors, officers and other affiliates may not be sold, transferred, assigned, pledged or hypothecated for three months following the effective date of this offering pursuant to rules of the Financial Industry Regulatory Authority;

2,355,303 shares of common stock that are held by our directors, officers and other affiliates that are subject to the 180-day lock-up period described below will be eligible for sale in the public market pursuant to Rule 144 following the expiration of the 180-day lock-up period described below;

1,324,266 shares of common stock that are held by our directors, officers and other affiliates and are not subject to the 180-day lock-up period described below will be eligible for sale in the public market pursuant to Rule 144; and

3,679,569 shares of our common stock are beneficially owned by directors, officers and affiliates and will be subject to volume and other restrictions of Rule 144 described below.

Lock-Up Agreements

Pursuant to certain lock-up agreements, we, our officers and directors, certain of our option holders and warrant holders, Efficacy Capital Ltd. and FMR, LLC have agreed, subject to certain limited exceptions, not to, for a period from the date of the final prospectus for this offering through and including the 180th day after the date of the final prospectus, offer, pledge, announce the intention to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any options, right or warrant to purchase or otherwise dispose of, directly or indirectly, any

Table of Contents

shares of our common stock or securities convertible into or exchangeable or exercisable for shares of our common stock or to file or request the filing of any registration statement under the Securities Act with respect of such shares. The 180-day restricted period will be automatically extended if (i) during the last 17 days before the last day of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period, in either of which case the restrictions described above will continue to apply until the expiration of the date that is 18 days after the issuance of the earnings release or the material news or material event occurs. These lock-up restrictions apply to our shares of our common stock and to securities convertible into or exchangeable or exercisable for or repayable with shares of our common stock. The lock-up restrictions will not apply to certain transfers not involving a disposition for value, provided that the recipient agrees to be bound by these lock-up restrictions. The lock-up restrictions will not apply to grants we may make under our existing stock options plans or to exercises of stock options under our stock options plans, but will apply to shares acquired upon exercise of these options. Piper Jaffray may agree, at any time or from time to time and without notice, to release for sale in the public market all or any portion of the securities subject to these restrictions.

Rule 144 described below does not supersede the contractual obligations of our security holders set forth in the lock-up agreements.

Stock Options

Based on options to purchase ordinary shares of Osmetech outstanding as of March 31, 2010 and assuming no options to purchase shares of Osmetech or GenMark are issued after that date, GenMark will have outstanding options to purchase an aggregate of 963,514 shares of common stock immediately following the Reorganization and this offering with a weighted-average exercise price of \$7.45 per share. Assuming all holders of options to purchase ordinary shares of Osmetech exchange their options for options to purchase shares of GenMark common stock, all of the outstanding options at the time of closing of this offering will be governed by the terms of the 2010 Plan. We intend to register all of the common shares issued or reserved for future issuance under the 2010 Plan by filing a Form S-8 registration statement under the Securities Act approximately 60 days following the effectiveness of this registration statement. After the effective date of the Form S-8, all common shares purchased upon exercise of the outstanding GenMark options generally will be available for resale in the public market, subject to the terms of the lock-up agreements.

Warrants

Based on warrants to purchase ordinary shares of Osmetech outstanding as of March 31, 2010 and assuming no warrants to purchase shares of GenMark are issued after that date, GenMark will have outstanding warrants to purchase an aggregate of 220,792 shares of common stock immediately following the Reorganization and this offering with a weighted-average exercise price of \$8.32 per share. All of the outstanding warrants are subject to lock-up agreements for a period of 180 days after the date of the final prospectus. Upon exercise of the warrants and the expiration of the lock-up period, the holder may sell the shares of common stock in the market in accordance with Rule 144 under the Securities Act.

Rule 144

Shares of our common stock issued to former shareholders of Osmetech who are not our directors, officers or other affiliates are freely tradeable and are not subject to the restrictions in Rule 144 of the Securities Act. In general, if there are any restricted shares, under Rule 144 under the Securities Act, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, a person who holds restricted shares of our common stock and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least six months,

Table of Contents

would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who holds restricted shares of our common stock and is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned these restricted shares for at least one year, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

one percent of the number of shares of our common stock then outstanding, which will equal approximately 117,235 shares immediately after this offering; and

the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, or if no such notice is required, the date of receipt of the order to execute the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Table of Contents

CERTAIN MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a discussion of the material U.S. federal income and estate tax considerations with respect to the ownership and disposition of our common stock that may be relevant to a non-U.S. holder that acquires our common stock pursuant to this offering. The discussion is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, applicable U.S. Treasury regulations promulgated thereunder and U.S. Internal Revenue Service, or IRS, rulings and pronouncements and judicial decisions, all as in effect on the date of this prospectus and all of which are subject to change (possibly on a retroactive basis) or to differing interpretations so as to result in tax considerations different from those summarized below. We can not assure you that a change in law will not alter significantly the tax considerations that we describe in this summary.

The discussion is limited to non-U.S. holders that hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). As used in this discussion, the term non-U.S. holder means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

an individual who is a citizen or resident of the United States;

a corporation including any entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States or any political subdivision thereof;

a partnership including any entity treated as a partnership for U.S. federal income tax purposes;

an estate, the income of which includes gross income for U.S. federal income tax purposes regardless of its source; or

a trust (1) if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) that has made a valid election to be treated as a U.S. person for such purposes.

This discussion does not address the U.S. federal income and estate tax rules applicable to any person who holds our common stock through entities treated as partnerships for U.S. federal income tax purposes or to such entities themselves. If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) owns our common stock, the tax treatment of a partner in that partnership will depend upon the status of the partner and the activities of the partnership. A holder that is a partnership or a holder of interests in a partnership should consult such holder's tax advisor regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion does not consider:

any state, local or foreign tax consequences;

any tax consequences or computation of the alternative minimum tax;

any U.S. federal gift tax consequences; or

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

any U.S. federal tax considerations that may be relevant to a non-U.S. holder in light of its particular circumstances or to non-U.S. holders that may be subject to special treatment under U.S. federal tax laws, including without limitation, banks or other financial institutions, insurance companies, tax-exempt organizations, certain trusts, hybrid entities,

Table of Contents

controlled foreign corporations, passive foreign investment companies, certain former citizens or residents of the U.S., holders subject to U.S. federal alternative minimum tax, broker-dealers, dealers or traders in securities or currencies and holders that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment.

Prospective investors are urged to consult their tax advisors regarding the application of the U.S. federal income and estate tax laws to their particular situations and the consequences under U.S. federal gift tax laws, as well as foreign, state and local laws and tax treaties.

Dividends

As previously discussed, we do not anticipate paying dividends on our common stock in the foreseeable future. If we pay dividends on our common stock, however, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed our current and accumulated earnings and profits, the distributions will constitute a return of capital and first reduce the non-U.S. holder's adjusted tax basis, but not below zero, and then will be treated as gain from the sale of stock, as described in the section of this prospectus entitled "Gain on Disposition of Common Stock."

A dividend paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate, or a lower rate under an applicable income tax treaty, unless the dividend is effectively connected with the conduct of a trade or business of the non-U.S. holder within the U.S. (and, if an applicable income tax treaty so requires, is attributable to a permanent establishment of the non-U.S. holder within the U.S.). Non-U.S. holders (generally on a properly executed IRS Form W-8 BEN) will be required to satisfy certain certification and disclosure requirements in order to claim a reduced rate of withholding pursuant to an applicable income tax treaty. These forms must be periodically updated. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. Special rules apply in the case of common stock held by certain non-U.S. holders that are entities rather than individuals.

Dividends that are effectively connected with a non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so requires, attributable to a permanent establishment in the United States will be taxed on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the non-U.S. holder were a resident of the United States. In such cases, we will not have to withhold U.S. federal income tax if the non-U.S. holder complies with applicable certification and disclosure requirements. In addition, a branch profits tax may be imposed at a 30% rate, or a lower rate under an applicable income tax treaty, on dividends received by a foreign corporation that are effectively connected with the conduct of a trade or business in the United States.

A non-U.S. holder may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund together with the required information with the IRS.

Gain on Disposition of Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless one of the following applies:

the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the U.S. and, if an applicable income tax treaty so requires, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the

Table of Contents

non-U.S. holder generally will be taxed on its net gain derived from the disposition at the regular graduated rates and in the manner applicable to United States persons and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above may also apply;

the non-U.S. holder is an individual present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met; in this case, the non-U.S. holder will be subject to a 30% tax on the amount by which the gain derived from the sale or other disposition of our common stock and any other U.S.-source capital gains realized by the non-U.S. holder in the same taxable year exceed the U.S.-source capital losses realized by the non-U.S. holder in that taxable year unless an applicable income tax treaty provides an exemption or a lower rate; or

we are or have been a U.S. real property holding corporation for U.S. federal income tax purposes at any time within the shorter of the five year period ending on the date of disposition or the period that the non-U.S. holder held our common stock. We do not believe that we have been, are, or will become, a U.S. real property holding corporation, although there can be no assurance in this regard. If we are, or were to become, a U.S. real property holding corporation at any time during the applicable period, however, any gain recognized on a disposition of our common stock by a non-U.S. holder that did not own (directly, indirectly or constructively) more than 5% of our common stock during the applicable period generally would not be subject to U.S. federal income tax, provided that our common stock is regularly traded on an established securities market (within the meaning of Section 897(c)(3) of the Code).

Federal Estate Tax

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specifically defined for U.S. federal estate tax purposes) at the time of death are considered U.S. situs assets includible in the individual's gross estate for U.S. federal estate tax purposes and therefore may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise. The United States federal estate tax was automatically repealed effective January 1, 2010, for the estates of decedents dying in the year 2010. Accordingly, at present, there is no United States federal estate tax. However, Congress could pass a law reinstating the estate tax that has retroactive effect. In addition, unless Congress acts to make the current repeal permanent, the estate tax will be reinstated with respect to decedents who die after December 31, 2010. In view of the continuing uncertainty regarding the federal estate tax law, prospective investors are urged to consult their tax advisors regarding the U.S. federal estate tax considerations of acquiring, holding, and disposing of common stock.

Information Reporting and Backup Withholding Tax

Dividends and proceeds from the sale or other taxable disposition of our common stock are potentially subject to backup withholding. In general, backup withholding will not apply to dividends on our common stock paid by us or our paying agents, in their capacities as such, to a non-U.S. holder if the holder has provided the required certification that it is a non-U.S. holder.

Generally, we must report to the IRS the amount of dividends paid, the name and address of the recipient, and the amount, if any, of tax withheld. Pursuant to income tax treaties or some other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

In general, backup withholding and information reporting will not apply to proceeds from the disposition of our common stock paid to a non-U.S. holder within the United States or conducted through certain U.S.-related financial intermediaries the holder has provided the required certification that it is a non-U.S. holder.

Table of Contents

Backup withholding is not an additional tax. Any amount withheld may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided that the required information is furnished to the IRS in a timely manner.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the particular tax consequences to them of owning and disposing of our common stock, including the consequences under the laws of any state, local or foreign jurisdiction or under any applicable tax treaty.

Table of Contents**UNDERWRITING**

The underwriters named below have agreed to buy, subject to the terms of the purchase agreement, the number of shares listed opposite their names below. The underwriters are committed to purchase and pay for all of the shares if any are purchased.

Underwriters	Number of Shares
Piper Jaffray & Co.	3,220,000
William Blair & Company, L.L.C.	920,000
ThinkEquity LLC	460,000
Total	4,600,000

The underwriters have advised us that they propose to offer the shares to the public at \$6.00 per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than \$0.252 per share. The underwriters may allow and the dealers may reallocate a concession of not more than \$0.10 per share on sales to certain other brokers and dealers. After the offering, these figures may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

We have granted the underwriters an option to purchase up to 690,000 additional shares of common stock from us at the same price to the public, and with the same underwriting discount, as set forth in the table below. The underwriters may exercise this option at any time and from time to time during the 30-day period from the date of this prospectus to cover over-allotments, if any. To the extent any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above.

The following table shows the underwriting fees to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	No Exercise	Full Exercise
Per Share	\$ 0.42	\$ 0.42
Total	\$ 1,932,000	\$ 2,221,800

We estimate that the total fees and expenses of the offering, excluding underwriting discounts, will be approximately \$1.7 million.

GenMark and Osmetech, which will become a subsidiary controlled by GenMark immediately prior to the closing of this offering, have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

We, each of our directors and executive officers and certain of our stockholders are subject to lock-up agreements that prohibit us and them from offering, pledging, announcing the intention to sell, selling, contracting to sell, selling any option or contract to purchase, purchasing any option or contract to sell, granting any option, right or warrant to purchase, making any short sale or otherwise transferring or disposing of, directly or indirectly, any shares of our common stock or any securities convertible into, exercisable or exchangeable for or that represent the right to receive our common stock or entering into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, for a period of at least 180 days following the date of this prospectus

Table of Contents

without the prior written consent of Piper Jaffray. The lock-up agreement does not prohibit our directors, executive officers or other stockholders party to a lock-up agreement from transferring shares of our common stock as a bona fide gift or to certain trusts, subject to certain requirements, including that the transferee be subject to the same lock-up terms, or pursuant to Rule 10b5-1 trading plans in existence as of the date of this prospectus. The lock-up provisions do not prevent us from selling shares to the underwriters pursuant to the underwriting agreement, from granting options to acquire securities under our existing stock option plans or issuing shares upon the exercise or conversion of securities outstanding on the date of this prospectus or from issuing shares in connection with the scheme of arrangement described above in **Shares Eligible for Future Sale Lock-Up Agreements**.

The 180-day lock-up period in all of the lock-up agreements is subject to extension if (i) during the last 17 days of the lock-up period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions imposed in these lock-up agreements shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, unless Piper Jaffray waives the extension in writing.

The common shares of Osmetech have been traded on the Alternative Investment Market of the London Stock Exchange since 2002. Our common stock sold in this offering is listed on the NASDAQ Global Market. Prior to this offering, there has been no established trading market for our common stock. The initial public offering price for the shares of common stock offered by this prospectus was negotiated by us and the underwriters. The factors considered in determining the initial public offering price include the history of and the prospects for the industry in which we compete, the past and present operations of Osmetech and its subsidiaries, the historical results of operations of Osmetech and its subsidiaries, our prospects for future earnings, the recent market prices of ordinary shares of Osmetech and of securities of companies generally comparable to Osmetech and the general condition of the securities markets at the time of the offering and other relevant factors. There can be no assurance that the initial public offering price of our common stock will correspond to the price at which the common stock will trade in the public market subsequent to this offering or that an active public market for our common stock will develop and continue after this offering.

To facilitate the offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock during and after the offering. Specifically, the underwriters may over-allot or otherwise create a short position in our common stock for their own account by selling more shares of common stock than we have sold to them. The underwriters may close out any short position by either exercising their option to purchase additional shares or purchasing shares in the open market.

In addition, the underwriters may stabilize or maintain the price of the common stock by bidding for or purchasing shares of common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if shares of common stock previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of our common stock to the extent that it discourages resales of the common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

At our request, the underwriters have reserved shares of our common stock for sale in this offering, at the initial offering price, to our directors, employees and Ronin Capital L.L.C. Christopher Gleeson, one

Table of Contents

of our directors, has advised us that he expects to purchase \$8,000,000 of our common stock in this offering, or 1,333,333 shares based on the initial public offering price of \$6.00 per share, for investment purposes. Jon Faiz Kayyem, our President and Chief Executive Officer and one of our directors, has advised us that he expects to purchase up to \$1,500,000 of our common stock in this offering, or 250,000 shares based on the initial public offering price of \$6.00 per share, for investment purposes. Daryl Faulkner, one of our directors, and John Bellano, our Senior Vice President of Commercial Operations, have also advised us that they expect to purchase up to \$100,000 and \$50,000, respectively, of our common stock in this offering, or 16,666 and 8,333 shares, respectively, based on the initial public offering price of \$6.00 per share, for investment purposes. Another of our employees has advised us that she expects to purchase \$500,000 of our common stock in this offering, or 83,333 shares based on the initial public offering price of \$6.00 per share. Shares purchased by Messrs. Kayyem, Gleeson, Faulkner and Bellano would be subject to lock-up agreements as described under **Shares Eligible for Future Sale** **Lock-Up Agreements**. Our other directors and employees may also purchase shares in this offering.

Ronin Capital L.L.C. and its affiliated entities have committed to purchase 332,238 shares in this offering, which represents approximately the number of shares necessary for Ronin Capital's percentage ownership of our company to remain the same before and after this offering. Pursuant to the rules of the Financial Industry Regulatory Authority, shares purchased by Ronin Capital and its affiliates in this offering may not be sold, transferred, assigned, pledged or hypothecated for a period of three months following the effective date of this offering.

From time to time in the ordinary course of their respective businesses, the underwriters and certain of their respective affiliates have engaged, and may in the future engage, in commercial banking or investment banking transactions with us and our affiliates.

This prospectus may be made available on the web sites maintained by the underwriters and the underwriters may distribute prospectuses electronically.

Selling Restrictions

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a **Relevant Member State**), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, no offer of our common stock has been made or will be made to the public in that Relevant Member State, except that, with effect from and including such date, an offer of our common stock may be made to the public in the Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;

to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

Table of Contents

For the purposes of this provision, the expression an offer of our common stock to the public in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase any such shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Hong Kong

Our common stock may not be offered or sold by means of any document other than: (a) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong); (b) to professional investors as defined in the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules thereunder; or (c) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance. No advertisement, invitation or other document relating to our common stock may be issued, whether in Hong Kong or elsewhere, where such document is directed at, or the contents are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the laws of Hong Kong), other than with respect to such common stock that is intended to be disposed of only to persons outside of Hong Kong or only to professional investors as defined in the Securities and Futures Ordinance and any rules thereunder.

United Kingdom

In the United Kingdom this document is being distributed only to, and is directed only at Qualified Investors who are permitted to carry on regulated activity in the United Kingdom by the UK Financial Services Authority under the Financial Services and Markets Act 2000 (as amended), persons whose ordinary activities for the purpose of their businesses involve them in buying, selling, subscribing for or underwriting such securities or making arrangements for another person to do so (whether as principal or agent) or advising on investments or other persons who are Investment Professionals within the meaning given in paragraph 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Persons who are not permitted to carry on such regulated activity may not rely on this document.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock we are offering will be passed upon for us by DLA Piper LLP (US), San Diego. Faegre & Benson LLP is counsel to the underwriters in connection with the offering.

EXPERTS

The financial statements of Osmetech as of December 31, 2009 and 2008 and for each of the three years in the period ended December 31, 2009 included in this prospectus have been audited by Deloitte LLP (UK), an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The balance sheet of GenMark included in this prospectus has been audited by Deloitte & Touche LLP (US), an independent registered public accounting firm, as stated in their report appearing herein. Such financial statement has been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION ABOUT US

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules, and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement on Form S-1 of which this prospectus forms a part, reference is made to the exhibit for a more complete description of the matters involved. When we complete this offering, we will also be required to file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. We anticipate making these documents publicly available, free of charge, on our website at www.genmarkdx.com as soon as practicable after filing such documents with the Securities and Exchange Commission.

You may read and copy any document that we file at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, this registration statement and our future filings filed electronically with the Securities and Exchange Commission are publicly available through its website at www.sec.gov.

Table of Contents

INDEX TO FINANCIAL STATEMENTS

GenMark Diagnostics, Inc. Financial Statement as of March 18, 2010

Report of Independent Registered Public Accounting Firm F-2

Balance Sheet as of March 18, 2010 F-3

Notes to Consolidated Financial Statement F-4

Osmetech plc Unaudited Condensed Consolidated Financial Statements as of March 31, 2010 and for the three months ended March 31, 2010 and 2009

Unaudited Condensed Consolidated Balance Sheets as of March 31, 2010 and December 31, 2009 F-5

Unaudited Condensed Consolidated Statements of Operations for the three months ended March 31, 2010 and 2009 F-6

Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2010 and 2009 F-7

Notes to Unaudited Condensed Consolidated Financial Statements F-8

Osmetech plc Consolidated Financial Statements as of December 31, 2009 and 2008 and for the years ended December 31, 2009, 2008 and 2007.

Report of Independent Registered Public Accounting Firm F-14

Consolidated Balance Sheets as of December 31, 2009 and 2008 F-15

Consolidated Statements of Operations For the Years Ended December 31, 2009, 2008 and 2007 F-16

Consolidated Statements of Comprehensive Income (loss) For the years ended December 31, 2009, 2008 and 2007 F-16

Consolidated Statements of Stockholders' Equity For the Years Ended December 31, 2009, 2008 and 2007 F-17

Consolidated Statements of Cash Flows For the Years Ended December 31, 2009, 2008 and 2007 F-18

Notes to Consolidated Financial Statements F-19

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholder of

GenMark Diagnostics, Inc.

Pasadena, California

We have audited the accompanying balance sheet for GenMark Diagnostics, Inc. (the Company) as of March 18, 2010. This financial statement is the responsibility of the Company's management. Our responsibility is to express an opinion on this financial statement 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 balance sheet is 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. An audit includes 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 balance sheet, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall balance sheet presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such balance sheet presents fairly, in all material respects, the financial position of GenMark Diagnostics, Inc. at March 18, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

San Diego, California

March 18, 2010

F-2

Table of Contents

GENMARK DIAGNOSTICS, INC.

BALANCE SHEET

As of March 18, 2010

ASSETS	
Cash	\$ 1
Total assets	\$ 1
LIABILITIES AND STOCKHOLDER S EQUITY	
Total liabilities	\$
Commitments and contingencies	
Stockholder s equity:	
Common stock, \$0.0001 par value; 100,000,000 shares authorized; 1,000 shares issued	
Preferred stock, \$0.0001 par value; 5,000,000 authorized, none issued	
Additional paid-in capital	1
Total stockholder s equity	1
Total liabilities and stockholder s equity	\$ 1

The accompanying notes are an integral part of this financial statement.

Table of Contents

GENMARK DIAGNOSTICS, INC.

NOTES TO FINANCIAL STATEMENT

1. Organization:

Genmark Diagnostics, Inc. (the Company or GenMark), formed on February 12, 2010, was established to serve as the parent company of Osmetech plc (Osmetech). Immediately prior to the closing of a proposed initial public offering (IPO) of GenMark shares, GenMark will acquire all of the outstanding shares of Osmetech by way of a reorganization under the applicable laws of the United Kingdom. In the reorganization, all of the issued shares of Osmetech will be cancelled in consideration of (i) the issuance of 1 share of common stock of GenMark to the former shareholders of Osmetech for each 230 ordinary shares of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech will be a subsidiary controlled by GenMark, and the former shareholders of Osmetech will hold shares of GenMark. In connection with the IPO, the Osmetech Plc ordinary shares will be exchanged for the common stock of GenMark on a 1:230 basis.

As this proposed reorganization is deemed to be a transaction under common control, GenMark will account for the reorganization in a manner similar to a pooling-of-interests, meaning:

- (i) assets and liabilities will be carried over at their respective carrying values;
- (ii) common stock will be carried over at the nominal value of the shares issued by GenMark;
- (iii) additional paid-in capital will represent 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 described reorganization; and
- (iv) the accumulated deficit will represent the aggregate of the accumulated deficit of Osmetech and GenMark.

Once the reorganization has become effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, Long Term Incentive Awards and all warrants issued will be 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.

Since the Company s formation on February 12, 2010, there has been no operating activity.

2. Basis of Presentation:

The accompanying financial statements have been prepared on the basis of accounting principles generally accepted in the United States of America.

Table of Contents

Osmetech plc

Condensed Consolidated Balance Sheets

(Unaudited)

	As of March 31, 2010	As of December 31, 2009
Current assets		
Cash and cash equivalents	\$ 11,321,012	\$ 16,482,818
Accounts receivable	241,158	169,842
Inventories	172,105	136,967
Other current assets	2,709,363	992,181
Total current assets	14,443,638	17,781,808
Property and equipment-net	1,568,732	1,381,618
Intangible assets-net of accumulated amortization	117,292	170,051
Total assets	\$ 16,129,662	\$ 19,333,477
Current liabilities		
Accounts payable	\$ 1,188,341	\$ 1,504,905
Accrued compensation	1,101,572	822,388
Other current liabilities	2,243,425	886,032
Total current liabilities	4,533,338	3,213,325
Long-term liabilities		
Other non-current liabilities	802,834	795,334
Total liabilities	5,336,172	4,008,659
Stockholders equity		
Ordinary shares, £0.001 (\$0.00151 and \$0.00158 as of March 31, 2010 and December 31, 2009, respectively) par value; 1,638,407,754 and 1,633,443,351 shares issued and outstanding as of March 31, 2010 and December 31, 2009, respectively	2,581,339	2,573,857
Deferred shares, £0.0099 (\$0.01709) par value; 689,478,300 shares issued and outstanding as of March 31, 2010 and December 31, 2009	11,780,709	11,780,709
Additional paid-in capital	127,820,232	127,475,450
Accumulated deficit	(130,938,834)	(126,089,889)
Accumulated other comprehensive loss	(449,956)	(415,309)
Total stockholders equity	10,793,490	15,324,818
Total liabilities and stockholders equity	\$ 16,129,662	\$ 19,333,477

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

Table of Contents

Osmetech plc

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Revenue		
Product sales	\$ 384,249	\$ 177,911
License revenue	15,015	10,389
Total revenue	399,264	188,300
Cost of sales	567,396	1,374,561
Gross loss	(168,132)	(1,186,261)
Operating expenses		
Sales and marketing	1,058,285	553,953
Research and development	1,453,759	1,430,348
General and administrative	2,167,264	1,457,434
Total operating expenses	4,679,308	3,441,735
Loss from operations	(4,847,440)	(4,627,996)
Other income		
Foreign exchange (loss) gain	(1,110)	131,766
Interest income	4,654	22,697
Total other income	3,544	154,463
Loss before income taxes	(4,843,896)	(4,473,533)
Benefit (provision) for income taxes	(5,049)	59,089
Net loss	\$ (4,848,945)	\$ (4,414,444)
Net loss per ordinary share, basic and diluted	\$ (0.003)	\$ (0.005)
Weighted average number of shares outstanding	1,636,201,969	891,607,157
Pro forma net loss per common share, (Post IPO Genmark shares)	\$ (0.68)	\$ (1.14)
Weighted average shares used in pro forma per share amounts	7,113,922	3,876,553
Condensed Consolidated statements of comprehensive loss three months ended March 31, 2010 and 2009		
Net loss	\$ (4,848,945)	\$ (4,414,444)
Foreign currency translation adjustment	(34,647)	(76,501)
Comprehensive loss	\$ (4,883,592)	\$ (4,490,945)

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

F-6

Table of Contents

Osmetech plc

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Three Months Ended March 31,	
	2010	2009
Cash flows from operating activities		
Net loss	\$ (4,848,945)	\$ (4,414,444)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	318,369	324,485
Impairment losses		549,148
Share-based compensation	347,530	(118,588)
Changes in operating assets and liabilities:		
Accounts receivable	(71,316)	23,114
Inventories	(65,138)	24,812
Other current assets	(469,561)	514,836
Accounts payable	(316,564)	(727,237)
Accrued compensation	279,184	24,942
Interest and income tax payable	7,500	(637)
Accrued and other liabilities	(163,224)	(596,560)
Net cash used in operating activities	(4,982,165)	(4,396,129)
Cash flows used in investing activities		
Purchases of property and equipment	(137,440)	(23,556)
Net cash used in investing activities.	(137,440)	(23,556)
Cash flow from financing activities		
Proceeds from stock option exercises	4,734	
Net cash provided by financing activities	4,734	
Net decrease in cash and cash equivalents	(5,114,871)	(4,419,685)
Cash and cash equivalents Beginning of period	16,482,818	8,822,458
Effect of foreign exchange rate changes	(46,935)	(214,740)
Cash and cash equivalents End of period	\$ 11,321,012	\$ 4,188,033
Supplemental cash flow disclosures:		
Cash paid for income taxes	\$ (5,049)	\$ (3,097)
Cash received for interest	\$ 4,654	\$ 1,325
Noncash investing and financing activities:		
Reclassification of deposits on instruments in other current assets, and inventory to property and equipment in 2010 and 2009, respectively	\$ 285,284	\$ 256,909

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

Costs incurred in conjunction with initial public offering	\$ 1,537,192	\$
--	--------------	----

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

F-7

Table of Contents

Osmetech plc

Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and basis of presentation

Osmetech plc (the Company) is a molecular diagnostics company focused on developing and commercializing the Company's proprietary e-sensor technology. On March 17, 2010, the Company's board of directors approved certain corporate governance changes necessary to allow the Company to proceed with a proposed initial public offering (IPO). Immediately prior to the completion of the proposed IPO, the Company will undergo a corporate reorganization whereby the ordinary shares of the Company will be exchanged by the current shareholders for the common stock of Genmark Diagnostics, Inc. (Genmark) on a 1:230 basis. Genmark, formed on February 12, 2010, was established to serve as the parent company of the Company following the corporate reorganization.

As a result of changes to UK Company Law (The Companies Act 2006), the requirement of UK companies to have authorized share capital was abolished with effect from October 1, 2009. As a result, the Company, does not have authorized share capital, and no further authorization is required in order to issue additional shares.

Basis of Presentation

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the three months ended March 31, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2009 included elsewhere in this prospectus.

The Company evaluated subsequent events through May 13, 2010 the date of issuance of the unaudited condensed consolidated financial statements.

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

The accompanying condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and had an accumulated deficit of \$130,938,834 at March 31, 2010. Cash and cash equivalents at March 31, 2010 were \$11,321,012.

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 management team has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of a line of credit of up to \$4,000,000, signed during March 2010, but excluding any proceeds from the proposed IPO, that the Company has sufficient capital to fund its operations for at least the next twelve months.

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

Table of Contents

Osmetech plc

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

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 and share-based compensation. Actual results could differ from those estimates.

New Accounting Pronouncements Adopted

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 instruments 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 instruments in the three months ended March 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 the effect of recognizing revenues of \$95,000, and had no material impact on loss per share during the three months ended March 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 three months ended March 31, 2010.

2. 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 awards, which are determined by 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.

Upon the closing of the proposed IPO, all of the outstanding shares of Osmetech plc, including options and warrants allowing for future purchase of Osmetech plc ordinary shares, will be converted into common stock, stock options and warrants exercisable into Genmark Diagnostics, Inc. common stock.

Table of Contents**Osmetech plc****Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

The Company has granted options under the Osmetech plc 2003 U.S. Equity Compensation Plan (the "U.S. Plan") and Long Term Incentive Awards (the "LTIPs") and has entered into individual option agreements that are outside the U.S. Plan.

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 Alternative Investment Market ("AIM") of the London Stock Exchange 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 March 31, 2010, 31,890,484 ordinary shares remained available for future grant of awards under the U.S. Plan.

The following table summarizes stock option activity during the three months ended March 31, 2010:

	Number of shares	Weighted average exercise price	Weighted average exercise price (translated to dollars)
Outstanding at December 31, 2009	228,439,284	£ 0.021	\$ 0.034
Granted			
Exercised	(4,964,403)	£(0.001)	\$ (0.002)
Cancelled	(1,866,751)	£ (0.001)	\$ (0.002)
Outstanding at March 31, 2010	221,608,130	£ 0.021	\$ 0.032

As of March 31, 2010, there were 221,608,130 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 9.7 years, and an aggregate intrinsic value of \$0.

3. 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 offers customers the choice to either purchase an instrument outright or to receive an instrument free of charge in exchange for an annual minimum purchase commitment for test cartridges. When an instrument is sold, revenue is generally recognized upon shipment of the unit. When an instrument is placed free of charge under a reagent rental agreement, the Company retains title to the equipment and the instrument remains capitalized on the balance sheet under property and equipment. Under the Company's reagent rental agreements, the Company retains the right to access or replace the instruments at any time and customers pay an additional instrument 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 instruments 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 instrument price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on instrument 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.

Table of Contents**Osmetech plc****Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

Arrangements that contain multiple deliverables including sales of instruments and test cartridges. These are accounted for as separate units of accounting because the instrument has value to the customer on a standalone basis and the agreements generally do not include a right of return relative to delivered products. Revenue is allocated to each element based on a relative estimated selling price because the Company is unable to establish selling price using VSOE or TPE. Determination of ESP involves weighting several factors based on the specific facts and circumstances of each arrangement. The factors include, but are not limited to, geographies, market conditions, gross margin objectives, pricing practices and controls and customer segment pricing strategies and the product lifecycle. The Company analyzes selling prices used in their allocation of arrangement consideration on an annual basis, or more frequently if necessary. Selling prices will be analyzed more frequently if a significant change in business necessitates a more timely analysis or if the Company experience significant variances in its selling prices.

During the three months ended March 31, 2010, the Company sold two XT-8 instruments.

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

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.

4. 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. There were no significant financial instruments requiring one-time or recurring measurements of fair value during the three months ended March 31, 2010.

During the three months ended March 31, 2009, a cash flow analysis indicated that certain of the Company's patent licenses may have been impaired and required that an assessment of the fair value of the patent licenses be performed. 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 three months ended March 31, 2009 as a result of these fair value measurements were \$549,148 for intangible assets.

5. Net Loss Per Ordinary Share

The computations of diluted net loss per ordinary share for the three months ended March 31, 2010 and 2009 do 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.

	Three months ended March 31,	
	2010	2009
Share options	221,608,130	63,349,575
Warrants	50,782,043	
	272,390,173	63,349,575

Table of Contents**Osmetech plc****Notes to Unaudited Condensed Consolidated Financial Statements (Continued)**

Share Warrants During 2009, the Company issued warrants to purchase 30,469,226 of the Company's ordinary shares with an exercise price of 2p per share, and warrants to purchase 20,312,817 of the Company's ordinary shares with an exercise price of 3p per share to a director for services to the Company in connection with the share offering completed in 2009. 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 Board (for whatever reason) and (ii) June 30, 2012. In the case of the warrants exercisable at 2p per share, they also cease to be exercisable upon the closing of a financing by the Company of an amount of U.S. \$20 million or more.

Additionally, 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 the Company. The deferred shares are non transferable. In the event of a return of assets on winding up of the Company, the deferred shareholders receive 1p in respect of their shareholding in its entirety.

Pro forma net loss per share is presented for additional information only. As disclosed in note 1 *Organization and basis of presentation*, GenMark will become the new parent company of the Company following the corporate reorganization. In connection with the IPO, the Osmetech plc ordinary shares will be exchanged for the common stock of GenMark on a 1:230 basis. Pro forma net loss from continuing operations per share is computed as if the 1:230 share exchange had occurred at the beginning of the periods presented.

6. 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.

7. Property and Equipment, net

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

	March 31, 2010	December 31, 2009
Property and equipment at cost:		
Plant, machinery and laboratory instruments	\$ 4,559,384	\$ 4,274,115
Office equipment	1,246,668	1,079,214
Leasehold improvements	74,394	74,394
Total property and equipment at cost	5,880,446	5,427,723
Less accumulated depreciation	(4,311,714)	(4,046,105)
Net property and equipment	\$ 1,568,732	\$ 1,381,618

The depreciation expense amounted to \$198,687 and \$283,538 for the three months ended March 31, 2010 and 2009, respectively.

Table of Contents

8. Note Payable

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 March 15, 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 March 31, 2010, the Company has not drawn any funds under this loan and security agreement.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Osmetech plc

London, United Kingdom

We have audited the accompanying consolidated balance sheets of Osmetech plc and subsidiaries (the Company) as of December 31, 2009 and 2008, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three 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 2008, and the results of their operations and their cash flows for each of the three 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

Table of Contents

Osmetech plc

Consolidated Balance Sheets as of December 31, 2009 and 2008

	As of December 31,	
	2009	2008
Current assets		
Cash and cash equivalents	\$ 16,482,818	\$ 8,822,458
Accounts receivable	169,842	118,774
Inventories	136,967	1,621,259
Other current assets	992,181	1,293,499
Total current assets	17,781,808	11,855,990
Property and equipment net	1,381,618	2,344,305
Intangible assets net of accumulated amortization	170,051	974,920
Total assets	\$ 19,333,477	\$ 15,175,215
Current liabilities		
Accounts payable	\$ 1,504,905	\$ 2,362,212
Accrued compensation	822,388	701,764
Other current liabilities	886,032	1,404,733
Total current liabilities	3,213,325	4,468,709
Long-term liabilities		
Other non-current liabilities	795,334	769,237
Total liabilities	4,008,659	5,237,946
Commitments and contingencies	See note 6	
Stockholders equity		
Ordinary shares, £0.001 (\$0.00158) par value; 1,633,443,351 and 891,607,157 shares issued and outstanding as of December 31, 2009 and 2008, respectively	2,573,857	1,367,062
Deferred shares, £0.0099 (\$0.01709) par value; 689,478,300 shares issued and outstanding as of December 31, 2009 and 2008.	11,780,709	11,780,709
Additional paid-in capital	127,475,450	103,238,405
Accumulated deficit	(126,089,889)	(106,127,280)
Accumulated other comprehensive loss	(415,309)	(321,627)
Total stockholders equity	15,324,818	9,937,269
Total liabilities and stockholders equity	\$ 19,333,477	\$ 15,175,215

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

Table of Contents

Osmetech plc

Consolidated Statements of Operations

For the Years ended December 31, 2009, 2008 and 2007

	2009	Year ended December 31, 2008	2007
Revenue			
Product sales	\$ 910,527	\$ 559,592	\$ 234,099
License revenue	87,889	87,500	107,500
Total revenue	998,416	647,092	341,599
Cost of sales	4,332,299	3,237,869	2,624,589
Gross loss	(3,333,883)	(2,590,777)	(2,282,990)
Operating expenses			
Sales and marketing	3,181,762	3,393,665	2,220,098
Research and development	5,633,717	13,423,679	12,554,236
General and administrative	8,288,762	9,632,708	8,895,796
Total operating expenses	17,104,241	26,450,052	23,670,130
Loss from operations	(20,438,124)	(29,040,829)	(25,953,120)
Other income			
Foreign exchange gain	303,523	504,921	
Interest income	33,222	420,011	1,715,211
Total other income	336,745	924,932	1,715,211
Loss before income taxes	(20,101,379)	(28,115,897)	(24,237,909)
Benefit (provision) for income taxes	138,770	(246,736)	300,214
Net loss from continuing operations	(19,962,609)	(28,362,633)	(23,937,695)
Loss from discontinued operations			(1,296,656)
Gain on sale of discontinued operations			35,779,149
Net income (loss)	\$ (19,962,609)	\$ (28,362,633)	\$ 10,544,798
Net income (loss) per ordinary share, basic and diluted	\$ (0.02)	\$ (0.12)	\$ 0.05
Net loss from continuing operations per ordinary share basic and diluted	\$ (0.02)	\$ (0.12)	\$ (0.12)
Weighted average number of ordinary shares outstanding (basic and diluted)	1,041,154,350	231,928,699	202,934,689
Unaudited pro forma net loss from continuing operations per common share, basic and diluted (Post IPO Genmark Shares)	\$ (4.41)	\$ (28.13)	\$ (27.13)
Weighted average shares used in unaudited pro forma per share amounts	4,526,758	1,008,386	882,325
Consolidated Statements of Comprehensive Income (Loss)			
For the Years ended December 31, 2009, 2008 and 2007			
Net income (loss)	\$ (19,962,609)	\$ (28,362,633)	\$ 10,544,798
Foreign currency translation adjustment	(93,682)	(1,157,707)	37,612

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

Comprehensive income (loss)	\$ (20,056,291)	\$ (29,520,340)	\$ 10,582,410
-----------------------------	-----------------	-----------------	---------------

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

F-16

Table of Contents**Osmetech plc****Consolidated Statements of Stockholders' Equity****For the Years ended December 31, 2009, 2008 and 2007**

		Ordinary Shares		Deferred Stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
		Shares	Par value	Shares	Par value				
Balance	January 1, 2007	202,804,973	\$ 359,940	689,478,300	\$ 11,780,709	\$ 93,729,703	\$ 798,468	\$ (88,309,445)	\$ 18,359,375
Share-based compensation related to stock options						1,188,191			1,188,191
Exercise of stock options on common stock		251,666	499			104,113			104,612
Repurchase of ordinary shares options						(266,900)			(266,900)
Foreign currency translation adjustment							37,612		37,612
Net income								10,544,798	10,544,798
Balance	December 31, 2007	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 share 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

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

Table of Contents

Osmetech plc

Consolidated Statements of Cash Flows

For the Years Ended December 31, 2009, 2008 and 2007

	Year ended December 31,		
	2009	2008	2007
Cash flows from operating activities			
Net income (loss)	\$ (19,962,609)	\$ (28,362,633)	\$ 10,544,798
Adjustments to reconcile net income (loss) to net cash used in operating activities			
Depreciation and amortization	1,569,074	1,157,655	985,204
Loss from disposal of property and equipment	8,462	31,335	38,606
Impairment losses	1,505,642		165,979
Share-based compensation	1,311,033	(256,219)	1,188,191
Gain on sale of discontinued operations			(35,779,149)
Changes in operating assets and liabilities:			
Accounts receivable	(51,068)	(21,056)	(30,860)
Inventories	1,227,383	(736,121)	(106,901)
Other current assets	315,985	(172,491)	694,324
Accounts payable	(857,307)	1,365,330	(663,505)
Accrued and other current liabilities	(510,168)	825,595	(3,735,971)
Net cash used in operating activities	(15,443,573)	(26,168,605)	(26,699,284)
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	(1,068,671)	(1,592,715)	(1,160,379)
Proceeds from sale of discontinued operations net of transaction costs			43,294,632
Purchases of intangible assets			(690,897)
Net cash provided by (used in) investing activities	(1,058,671)	(1,432,715)	41,443,356
Cash flows from financing activities			
Proceeds from the issuance of ordinary shares, net of offering expenses	24,132,807	9,723,182	
Proceeds from stock option exercises		22,959	104,612
Cash payments to redeem share warrants			(945,341)
Repurchase of share options related to discontinued business			(266,900)
Net cash provided by (used in) financing activities	24,132,807	9,746,141	(1,107,629)
Net increase (decrease) in cash and cash equivalents	7,630,563	(17,855,179)	13,636,443
Cash and cash equivalents Beginning of year	8,822,458	27,619,715	13,874,798
Effect of foreign exchange rate changes	29,797	(942,078)	108,474
Cash and cash equivalents End of year	\$ 16,482,818	\$ 8,822,458	\$ 27,619,715
Supplemental cash flow disclosures:			
Cash received (paid) for income taxes	\$ 181,162	\$ 391,086	\$ (368,194)
Cash received for interest	\$ 33,222	\$ 420,011	\$ 1,715,211

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

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements

1. Organization and basis of presentation

Osmetech plc ("Osmetech") is a company incorporated in the United Kingdom under the Companies Act 1985. Osmetech and its subsidiaries are referred to collectively as the "Company" . The Company is a molecular diagnostics company focused on developing and commercializing the Company's proprietary e-sensor technology.

On March 17, 2010, the Company's board of directors approved certain corporate governance changes necessary to allow the Company to proceed with a proposed initial public offering ("IPO") on NASDAQ. Immediately prior to the completion of the proposed IPO, the Company will undergo a corporate reorganization whereby the ordinary shares of the Company will be exchanged by the current shareholders for the common stock of Genmark Diagnostics, Inc. ("Genmark") on a 1:230 basis. Genmark, formed on February 12, 2010, was established to serve as the parent holding company of the Company.

As a result of changes to UK Company Law (The Companies Act 2006), the requirement of UK companies to have authorized share capital was abolished with effect from October 1, 2009. As a result, the Company, does not have authorized share capital, and no further authorization is required in order to issue additional shares.

Subsequent events have been evaluated through March 19, 2010, being the date that the financial statements were 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 \$126,089,889 at December 31, 2009. Cash and cash equivalents at December 31, 2009 were \$16,482,818.

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 management team has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of a line of credit of up to \$4,000,000, signed during March 2010, but excluding any proceeds from the proposed IPO, 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, 2009 are not necessarily indicative of the results that may be expected for any future periods.

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.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)****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. The Company has not historically reserved or written-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 certain finished goods inventory, and determined that they would likely be placed free of charge 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
Instruments 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.

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements (Continued)

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 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 instruments 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 instruments at any time. Therefore, the instruments 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.

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.

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. An allowance is provided to reduce deferred tax assets to the amount management believes will, more likely than not, be recovered.

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

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements (Continued)

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

The functional currency of the Company's operations in the U.S. is the U.S. dollar, and the functional currency of the U.K. based parent is the British Pound Sterling. Monetary assets and liabilities of the Company's entities outside of the U.S. are translated into U.S. dollars based on foreign currency exchange rates in effect at the end of each period, and revenues and expenses are translated at weighted average exchange rates during the periods. Gains or losses resulting from these foreign currency translations of the Company's assets and liabilities are recorded in accumulated other comprehensive income in the consolidated balance sheets.

Transactions in foreign currencies are translated into the relevant functional currency at the rate of exchange prevailing at the date of the transaction. Foreign currency transaction gains, which are included in the results of operations, totaled \$303,523, \$504,921, and \$0 for the years ended December 31, 2009, 2008, and 2007, respectively, and relate primarily to transactions denominated in U.S. dollars which were undertaken by the U.K. based parent.

Derivative Financial Instruments

Derivative financial instruments are used principally in the management of foreign currency and interest rate exposures and are recorded in the consolidated balance sheets at fair value. Derivative instruments not designated as hedges are marked-to-market at the end of each accounting period with the results included in results of operations. The effect on earnings in the periods presented was not material.

Net Loss Per Ordinary Share

Basic net loss per share is computed by dividing loss available to ordinary shareholders (the numerator) by the weighted average number of ordinary 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 ordinary shares that would have been outstanding if the dilutive potential ordinary shares had been issued unless the effect would be anti-dilutive. As the Company had a net loss from continuing operations in each of the periods presented, basic and diluted net loss per ordinary share are the same.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

The computations of diluted net loss per ordinary share for the years ended December 31, 2009, 2008 and 2007 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,		
	2009	2008	2007
Share options	228,439,284	24,975,790	30,498,838
Warrants	50,782,043		
	279,221,327	24,975,790	30,498,838

Additionally, Deferred Shares, which were created at the time of a 10-for-1 consolidation of common 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 thereof to payment of any dividend or other distribution or to receive notice or attend or vote at any general meeting of the Company. The deferred shares are non transferable. In the event of a return of assets on winding up of the Company, the deferred shareholders receive 1p in respect of their shareholding in its entirety.

Unaudited pro forma net loss per share is presented for additional information only. As disclosed in note 1 *Organization and basis of presentation*, GenMark will become the new holding company for the Company. In connection with the IPO, the Osmetech plc ordinary shares will be exchanged for the common stock of GenMark on a 1:230 basis. Pro forma net loss from continuing operations per share is computed as if the 1:230 share exchange had occurred at the beginning of the periods presented.

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.

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

	Year Ended December 31,		
	2009	2008	2007
Customer A	15%	13%	
Customer B	12%	23%	
Customer C		18%	31%
Customer D	11%		
Customer E			15%
Customer F			17%

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.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)****Recent Accounting Pronouncements**

In October 2009, authoritative guidance was provided on revenue arrangements with multiple deliverables. Under this guidance, when vendor specific objective evidence or third-party evidence for deliverables in an arrangement cannot be determined, a best estimate of the selling price is required to separate deliverables and allocate arrangement consideration using the relative selling price method. The guidance also includes new disclosure requirements on how the application of the relative selling price method affects the timing and amount of revenue recognition. This guidance is to be applied on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. The Company is currently evaluating the impact of the implementation on its results of operations, cash flows and financial condition.

3. Intangible assets

Intangible assets, consisting of purchased intellectual property, as of December 31, 2009 and 2008 comprise the following:

	December 31, 2009			December 31, 2008		
	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	\$ (437,640)	\$ 392
Intellectual property	877,140	(877,140)		877,140	(877,140)	
Licenses	1,251,518	(1,081,467)	170,051	1,251,518	(276,990)	974,528
	\$ 2,566,690	\$ (2,396,639)	\$ 170,051	\$ 2,566,690	\$ (1,591,770)	\$ 974,920

Licenses have a weighted average remaining amortization period of 4 years as of December 31, 2009. Amortization expense for intangible assets amounted to \$164,662, \$105,455, and \$81,090 for the years ended December 31, 2009, 2008, and 2007, 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,	
2010	\$ 92,577
2011	\$ 18,245
2012	\$ 11,750
2013	\$ 11,750
2014	\$ 11,750
Thereafter	\$ 23,979

4. Share-based compensation

Upon the closing of the anticipated NASDAQ common stock offering, all of the outstanding shares of Osmetech plc, including options and warrants allowing for future purchase of Osmetech plc ordinary shares, will be converted into common stock, stock options and warrants exercisable into Genmark Diagnostics, Inc. common stock.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

The Company has granted options under the Osmetech plc 2003 U.S. Equity Compensation Plan (the U.S. Plan) and Long Term Incentive Awards (the LTIPs) and has entered into individual option agreements that are outside the U.S. Plan.

Employee participation is at the discretion of the compensation committee or senior management of the Company. Options to purchase 6,331,154 shares granted under LTIPs and outside the U.S. Plan, options are exercisable at a price of 0.1 pence (p) per share subject to the achievement of specific non-market based performance criteria. All other options are exercisable at a price equal to the average closing quoted market price of the Company's shares 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, 2009, 31,140,484 ordinary shares remain available for future grant of awards under the U.S. Plan.

The following table summarizes stock option activity during the year ended December 31, 2009:

	Number of shares	Weighted average exercise price	Weighted average exercise price (translated to dollars)
Outstanding at December 31, 2008	24,975,790	£0.062	\$ 0.091
Granted	262,398,130	£0.020	\$ 0.033
Exercised			
Cancelled	(58,934,636)	£0.035	\$ (0.057)
Outstanding at December 31, 2009	228,439,284	£0.021	\$ 0.034
Exercisable at December 31, 2009	8,615,094	£0.035	\$ 0.056

Included in the above are approximately 32,600,000 of options which were cancelled and re-granted during the year. This was treated as a modification of the original options, and did not result a significant compensation charge.

The weighted average fair value of options granted during 2009, 2008 and 2007 was \$0.016, \$0.119 and \$0.173, respectively. The intrinsic value of options exercised in 2008 and 2007 was \$3,116, and \$285,546, respectively. No options were exercised in 2009. As of December 31, 2009, there were 228,439,284 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 9.82 years, and an aggregate intrinsic value of \$0. Options that are exercisable as of December 31, 2009 have a remaining weighted average contractual term of 7.11 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, 2009, 2008 and 2007 with the following assumptions:

	Year Ended December 31,		
	2009	2008	2007
Vesting period (years)	3.2	3.0	3.1
Expected volatility (%)	66.7	49.0	50.7
Expected life (years)	0.4	3.0	3.5
Risk free rate (%)	2.2	4.6	5.3
Expected dividend yield (%)	0	0	0

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

Share Warrants During 2009, the Company issued warrants to purchase 30,469,226 ordinary shares of the Company's shares at a price of 2p per share, and warrants to purchase 20,312,817 ordinary shares of the Company's share at a price of 3p per share to a director for services to the Company in connection with the share offering completed in 2009. 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 Board (for whatever reason) and (ii) June 30, 2012. In the case of the warrants exercisable at 2p per share, they also cease to be exercisable upon the closing of a financing by the Company of an amount of U.S. \$20 million or more.

The resulting charge from these warrants in 2009 of \$929,444 was recorded in general and administrative expenses, and was determined using a Black-Scholes pricing model, using the following assumptions for the 2p and 3p options:

	2p	3p
Vesting period (years)	0	0
Expected volatility (%)	66.7	66.7
Expected life (years)	1	3
Risk free rate (%)	0.7	2.3
Expected dividend yield (%)	0	0

In 2007, the Company repurchased warrants exercisable for ordinary shares that had previously been issued as part of the consideration for a business combination. These warrants were classified as liabilities, with adjustments to the fair value of these options being recognized in the statement of operations. There was no material movement in the fair value of these warrants between January 1, 2007 and their repurchase.

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

	Year Ended December 31,		
	2009	2008	2007
Cost of sales	\$ 19,364	\$ 23,243	\$ 63,817
Sales and marketing	37,344	44,826	123,075
Research and development	48,409	58,107	159,541
General and administrative	1,205,916	(382,395)	516,283
	\$ 1,311,033	\$ (256,219)	\$ 862,716

Additionally, \$325,475 of share-based compensation was recognized from discontinued operations in the year ended December 31, 2007.

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, 2009, 2008 and 2007. 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, 2009, the estimated total remaining unamortized compensation expense, net of forfeitures, associated with share-based awards was \$2,380,016 which is expected to be recognized over a weighted-average period of 3.5 years.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)****5. Income Taxes**

The components of income (loss) before income taxes were as follows :

	Year Ended December 31,		
	2009	2008	2007
Domestic (U.S. Entities)	\$ (18,332,641)	\$ (25,585,488)	\$ (19,181,623)
Foreign (Non U.S. Entities)	(1,768,738)	(2,530,409)	(5,056,286)
	\$ (20,101,379)	\$ (28,115,897)	\$ (24,237,909)

The components of the income tax benefit for continuing operations are as follows for the years ended December 31, 2009, December 31, 2008 and December 31, 2007:

	Year Ended December 31,		
	2009	2008	2007
Current expense (benefit):			
U.S.	\$ (165,339)	\$	\$
State	2,872	8,583	
Foreign (Non-U.S. entities)		180,023	(300,214)
Total current expense (benefit)	(162,467)	188,606	(300,214)
Non-current expense:			
U.S.			
State	23,697	58,130	
Foreign (Non-U.S. entities)			
Total non-current expense	23,697	58,130	
Deferred expense (benefit):			
U.S.			
State			
Foreign (Non-U.S. entities)			
Total deferred expense			
Total expense (benefit)	\$ (138,770)	\$ 246,736	\$ (300,214)

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

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

	Year Ended December 31,		
	2009	2008	2007
Current deferred income tax assets (liabilities):			
Compensation accruals	\$ 82,262	\$ 95,135	\$ 534,480
Accruals and reserves	568,189	837,665	824,656
State tax provision	1,251	8,099	51,588
Valuation allowance	(651,702)	(940,899)	(1,410,724)
Total current deferred income taxes			
Noncurrent deferred income tax assets (liabilities):			
Property and equipment and intangible assets	1,068,097	(98,712)	(23,948)
Intercompany interest expense	2,140,075	2,006,305	2,408,932
NOL and credits	34,941,648	26,949,147	18,707,490
Valuation allowance	(38,149,820)	(28,856,740)	(21,092,474)
Total noncurrent deferred income taxes			
Net deferred income taxes	\$	\$	\$

A reconciliation of income tax (expense) benefit for continuing operations to the amount computed by applying the statutory federal income tax rate (the U.S. federal rate has been utilized as the Company's primary operations are taxed at the U.S. federal rate) to the loss from continuing operations is summarized as follows:

	2009	2008	2007
U.S. Federal statutory income tax rate	34.0 %	34.0%	34.0 %
Permanent differences	(0.09)%	(1.84)%	(0.08)%
State taxes	(0.13)%	(0.21)%	%
Effect of non-U.S. operations	(0.53)%	(0.49)%	(1.15)%
Effective rate change non-U.S.	(0.64)%	(2.09)%	%
Valuation allowance	(31.92)%	(30.25)%	(31.53)%
Total tax (benefit) provision	0.69 %	(0.88)%	1.24 %

As of December 31, 2009, the Company had net operating loss carryforwards of approximately \$62,531,646 and \$5,154,453 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 2029. In addition, the Company has non-U.S. net operating loss carryforwards of \$30,388,000. These losses are not subject to time limit restrictions.

Pursuant to Internal Revenue Code Section 382, use of the Company's NOL and credit carryforwards may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a moving three-year period. Ownership changes could impact the Company's ability to utilize NOL and credit carryforwards remaining at an ownership change date. The Company has not completed a 382 study at this time.

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

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

F-28

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

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, 2009. Such objective evidence limits the ability to consider other subjective evidence such as the projections for future growth. Based on this evaluation, as of December 31, 2009, a valuation allowance of \$38,801,522 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 the 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 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 FIN 48 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 FIN 48 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:

	2009	2008	2007
Balance at January 1	\$ 382,000	\$ 382,000	\$
Additions based on tax positions related to the current year			382,000
Balance at December 31	\$ 382,000	\$ 382,000	\$ 382,000

At December 31, 2009 and 2008, the Company classified \$463,000 and \$440,000, respectively, of total unrecognized tax benefits, which includes accrued interest and penalties of \$81,000 and \$58,000 for the years ended December 31, 2009 and 2008, 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 as income tax expense.

The Company is subject to taxation in the UK, U.S. and various states jurisdictions. As of December 31, 2009 the Company's tax years after 2007 are subject to examination by the UK tax authorities. With few exceptions, as of December 31, 2009, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2005.

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)****6. Commitments and Contingencies**

The Company has various operating lease agreements for its office, manufacturing, warehousing and laboratory space and equipment. Rent and operating expenses charged were \$1,124,655, \$1,228,173, and \$1,233,014 for the years ended December 31, 2009, 2008, and 2007, respectively. Pursuant to one of the Company's lease agreements 50 percent of the monthly rental for the period from February 2009 to December 2009 has been deferred. The balance deferred as at December 31, 2009 was \$186,949. The amount deferred bears interest at 6.5% per annum and is payable in full no later than December 31, 2010. The amount outstanding is secured on all personal property of Osmetech Molecular Diagnostics.

Annual future minimum obligations for operating leases as of December 31, 2009 are as follows:

Years Ending December 31,	Operating leases
2010	\$ 689,330
2011	184,821
2012	8,146
Total minimum lease payments	\$ 882,297

7. Inventory

Inventory on hand as of December 31, 2009 and 2008 was comprised of the following:

	2009	2008
Raw materials and work-in-process	\$ 70,035	\$ 1,094,228
Finished goods	66,932	527,031
	\$ 136,967	\$ 1,621,259

The reduction in raw materials and work-in-process during 2009 reflects the transfer of instrument inventory to property and equipment, which is expected to be utilized for purposes other than commercial sale, and the write down of inventory as a result of management's review for slow-moving and obsolete parts, when it was determined that certain items would not be saleable.

8. Property and Equipment, net

Property and equipment was comprised of the following as of December 31, 2009 and 2008:

	2009	2008
Property and equipment at cost:		
Plant, machinery and laboratory instruments	\$ 4,274,115	\$ 3,726,802
Office equipment	1,079,214	1,248,547

Edgar Filing: GenMark Diagnostics, Inc. - Form 424B4

Leasehold improvements	74,394	292,066
Total property and equipment at cost	5,427,723	5,267,415
Less accumulated depreciation	(4,046,105)	(2,923,110)
Net property and equipment	\$ 1,381,618	\$ 2,344,305

The depreciation expense amounted to \$1,404,412, \$1,052,200 and \$904,114 for the years ended December 31, 2009, 2008 and 2007 respectively.

During 2009, approximately \$256,909 of instruments were transferred out of finished goods inventory into property and equipment, net, when the Company changed its strategy from outright sales of

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements (Continued)

instruments to placing instruments with customers for no initial charge and recovering that cost through the sale of test cartridges pursuant to reagent rental agreements.

Due to the anticipated acceleration of the release of future generations of the Company's products, in particular the AD-8 System, the Company assessed all instruments for impairment. For instruments 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. Instruments 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 instruments placed with customers, \$69,959 was charged to research and development expenses in respect of instruments being used for research purposes, and \$129,712 was charged to sales and marketing expenses in respect of instruments being used for demonstration purposes only. Additionally in 2009, the Company revised the estimated useful life of instruments 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 expense was \$172,668, \$304,449, and \$254,901 for the years ended December 31, 2009, 2008 and 2007, respectively. Additionally, the Company has made contributions to other defined contribution plans on behalf of its employees amounting to \$58,004, \$98,325, and \$97,974 for fiscal 2009, 2008 and 2007, respectively.

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.

Accrued liabilities: The carrying value approximates fair value.

Foreign exchange contracts: The Company does not use derivative financial instruments for speculative or trading purposes. Where available, the Company enters into foreign exchange forward contracts to hedge certain balance sheet exposures and intercompany balances against future movement in foreign exchange rates. Gains and losses on the foreign exchange contracts are 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 require 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, 2009, 2008 and

Table of Contents**Osmetech plc****Notes to Consolidated Financial Statements (Continued)**

2007, the Company had outstanding foreign exchange forward contracts with aggregate notional amounts of \$0, \$6.0 million and \$0, 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 instruments. 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 instruments (note 8).

11. Discontinued operations***Critical Care Division***

In December 2006, the Company entered into a sale and purchase agreement to dispose of its Critical Care Division. The disposal was effected in order to generate cash flow for the expansion of the Company's other businesses. The disposal was completed on January 31, 2007, on which date control of the business passed to the acquirer. The fair value of the consideration received was \$43,294,632 which comprised cash consideration of \$45,358,000, less costs of \$2,063,368.

GeneSensor

During 2007, the development of the GeneSensor instrument platform was discontinued with the Company's resources fully focused on the eSensor technology and XT-8 platform. The GeneSensor technology was obtained as part of the acquisition of Molecular Sensing plc in 2004. Due to the decision to abandon the GeneSensor business, the Company impaired all of its assets related to GeneSensor with the related impairment charge being reported within discontinued operations. The impairment losses included the impairment of the property and equipment amounting to \$91,553 and the impairment of intangible assets amounting to \$74,426. All of these impairments have been reported in the loss attributable to the GeneSensor discontinued operation.

	Critical Care Division	GeneSensor	Total
Year Ended December 31, 2007			
Revenue	\$ 1,490,581	\$	\$ 1,490,581
Expenses	(2,255,391)	(365,867)	(2,621,258)
Impairment losses		(165,979)	(165,979)
Loss before and after income taxes	(764,810)	(531,846)	(1,296,656)
Profit on disposal of discontinued operations	36,488,149		36,488,149
Attributable tax expense	(709,000)		(709,000)
Net profit/ loss attributable to discontinued operations, net of tax	\$ 35,014,339	\$ (531,846)	\$ 34,482,493

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements (Continued)

Both basic and diluted net income per share related to discontinued operations in 2007 amounted to \$0.17 per share, and exclude the effects of the anti-dilutive shares described in Note 2 as the Company had net losses from continuing operations during the year.

The carrying amount of the major classes of assets and liabilities of the Critical Care Division included as part of the disposal group as of January 31, 2007 was as follows:

	Total
Goodwill	\$ 533,498
Property and equipment	1,695,482
Inventories	3,443,361
Accounts receivables	2,684,602
	8,356,943
Accounts payable	(1,163,078)
Net assets as of January 31, 2007, the date of disposal	\$ 7,193,865

12. Other Current Assets and Liabilities, and other non-current liabilities consisted of the following as of December 31, 2009, and 2008:

	2009	2008
Other Current Assets		
Deposits	\$ 344,558	\$ 706,667
Other	647,623	586,832
Total	\$ 992,181	\$ 1,293,499
Other Current Liabilities		
Accrued professional fees	\$ 544,524	\$ 271,206
Rental related liabilities	188,070	
Other	153,438	1,133,527
Total	\$ 886,032	\$ 1,404,733
Other non-current liabilities		
Rental related liabilities	\$ 332,334	\$ 329,237
Liability pertaining to uncertain tax position	463,000	440,000
Total	\$ 795,334	\$ 769,237

13. Subsequent Events

On February 8, 2010, the Company entered into a seven year seven month lease for a new 31,098 square foot facility in Carlsbad, California. The facility is part of a 3-building office and research and development project commonly known as "The Campus" located and addressed at 5964 La Place Court, Carlsbad, California, and comprising a total of approximately 158,733 rentable square feet. Monthly rental payments of \$45,092 commence upon the date of substantial completion of the tenant improvements in the premises and increase 3% annually thereafter. The Company also pays its prorata share of the building and project maintenance, property tax, management and other costs subject to certain limitations. The Company has paid a \$55,000 security deposit and provided a \$500,000 standby letter of credit as security for the future rent as well as 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 the company's building, subject to certain limitations.

Table of Contents

Osmetech plc

Notes to Consolidated Financial Statements (Continued)

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to which it 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 March 15, 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 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.

Pursuant to the terms of the loan and security agreement, the Company is required to maintain certain minimum cash ratios based upon the total cash balance and whether there are any outstanding amounts borrowed against the revolving line of credit or term loan. In addition, the loan and security agreement includes several restrictive covenants, including requirements that the Company obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to its property, making distributions to its stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. To secure the credit facility, the Company granted Square 1 Bank a first priority security interest in its assets and intellectual property rights. As of March 19, 2010, we had not drawn down any funds under the credit facility or the term loan.

Table of Contents

4,600,000 Shares
GENMARK DIAGNOSTICS, INC.
Common Stock

PROSPECTUS

Until June 26, 2010, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a

prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Sole Book-Running Manager

Piper Jaffray

William Blair & Company

ThinkEquity LLC

June 1, 2010