GenMark Diagnostics, Inc.
Form 10-Q
May 08, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

or

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

For the transition period from to

Commission File Number: 001-34753

GenMark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

The number of outstanding shares of the registrant s common stock on May 1, 2013 was 32,770,392.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

GenMark Diagnostics, Inc.

Condensed Consolidated Balance Sheets

(In thousands, except par value)

(Unaudited)

	As of March 31, 2013	As of December 31, 2012
Current assets		
Cash and cash equivalents	$ 32,017	$ 51,250
Investments	11,786	
Restricted Cash	1,094	1,343
Accounts receivable net of allowance of $38 and $30	4,363	3,190
Inventories	3,175	1,993
Other current assets	382	226
Total current assets	52,817	58,002
Property and equipment, net	7,347	7,074
Intangible assets, net	2,566	1,832
Other long-term assets	1,108	1,108
Total assets	$ 63,838	$ 68,016
Current liabilities		
Accounts payable	$ 2,315	$ 2,445
Accrued compensation	1,791	3,076
Current portion of loan payable	353	638
Other current liabilities	3,515	3,015
Total current liabilities	7,974	9,174
Long-term liabilities		
Loan payable, net of current portion	59	63
Other noncurrent liabilities	2,300	2,329
Total liabilities	10,333	11,566
Stockholders equity		
Common stock, $0.0001 par value; 100,000 authorized; 32,750 and 32,753 shares issued and outstanding as of March 31, 2013 and December 31, 2012, respectively	3	3
Preferred stock, $0.0001 par value; 5,000 authorized, none issued		
Additional paid-in capital	248,683	247,449
Accumulated deficit	(194,741)	(190,566)
Accumulated other comprehensive loss	(440)	(436)
Total stockholders equity	53,505	56,450
Total liabilities and stockholders equity	$ 63,838	$ 68,016

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

Table of Contents

GenMark Diagnostics, Inc.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Revenue		
Product revenue	$ 10,968	$ 2,120
License and other revenue	133	39
Total revenue	11,101	2,159
Cost of sales	5,034	1,687
Gross profit	6,067	472
Operating expenses		
Sales and marketing	2,359	1,418
General and administrative	2,558	2,587
Research and development	5,381	1,949
Total operating expenses	10,298	5,954
Loss from operations	(4,231)	(5,482)
Other income (expense)		
Interest income (expense), net	68	(20)
Other expense	(5)	(24)
Total other income (expense)	63	(44)
Loss before income taxes	(4,168)	(5,526)
Provision for income taxes	(7)	(32)
Net loss	$ (4,175)	$ (5,558)
Net loss per share, basic and diluted	(0.13)	(0.28)
Weighted average number of shares outstanding	31,835	20,094
Other Comprehensive Loss		
Net loss	$ (4,175)	$ (5,558)
Net unrealized loss on investments	(4)	
Comprehensive loss	$ (4,179)	$ (5,558)

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

4

Table of Contents

GenMark Diagnostics, Inc.

Condensed Consolidated Statement of Cash Flows

(In thousands)

(Unaudited)

	Three months ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$ (4,175)	$ (5,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	498	264
Share-based compensation	697	506
Bad debt provision	29	(28)
Non-cash inventory adjustments	403	(636)
Changes in operating assets and liabilities:		
Accounts receivable	(1,202)	72
Inventories	(1,531)	757
Other current assets	(116)	165
Accounts payable	129	(112)
Accrued compensation	(856)	(188)
Other liabilities	20	(738)
Net cash used in operating activities	(6,104)	(5,496)
Cash flows from investing activities		
Restricted cash	249	
Purchase of available-for-sale securities	(13,848)	
Payments for intellectual property licenses	(345)	(739)
Purchases of property and equipment	(1,003)	(17)
Proceeds from sales of marketable securities	2,000	
Maturity of short-term investment		5,000
Net cash (used in) provided by investing activities	(12,947)	4,244
Cash flows from financing activities		
Principal repayment of borrowings	(287)	(267)
Proceeds from stock exercises	105	
Net cash used in financing activities	(182)	(267)
Net decrease in cash and cash equivalents	(19,233)	(1,519)
Cash and cash equivalents at beginning of period	51,250	25,320
Cash and cash equivalents at end of period	$ 32,017	$ 23,801
Non-cash investing and financing activities:		
Property and equipment purchased with capital lease	$	$ 109
Transfer of systems from property and equipment into inventory	$ 54	$ 47
Property and equipment costs incurred but not paid included in other current liabilities	$ 333	$ 728

Intellectual property acquisition included in accrued liabilities	$	453	$	
Supplemental cash flow disclosures:				
Cash received for interest	$	75	$	
Cash paid for interest	$	7	$	

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

Table of Contents

Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

(unaudited)

1. Organization and basis of presentation

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

As the reorganization was deemed to be a transaction under common control, GenMark accounted for the reorganization in a manner similar to a pooling-of-interests, meaning:

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

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

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

iv. the accumulated deficit represented the aggregate of the accumulated deficit of Osmetech and GenMark.

Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term incentive awards and all warrants issued by Osmetech were exchanged for options and warrants exercisable for the common stock of the Company.

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

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $194.7 million at March 31, 2013. Cash and cash equivalents at March 31, 2013 was $32 million. The Company has prepared cash flow forecasts which indicate, based on the Company s current cash resources available, that the Company will have sufficient resources to fund its business for at least the next 12 months.

Management expects operating losses to continue through the foreseeable future until the Company has expanded its product offering and consequently increased its product revenues to an extent necessary to cover the fixed cost base of the business. The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of credit facilities, that the Company has sufficient capital to fund its operations for at least the next 12 months.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, and applicable regulations of the Securities and Exchange Commission, or the SEC. The Company s operating results for the three months ended March 31, 2013 are not necessarily indicative of the results that may be expected for any future periods.

Segment Information

The Company currently operates in one business segment which encompasses the development, manufacturing, marketing, sales and support of instruments and molecular tests based on its proprietary eSensor® detection technology. Although the Company offers multiple tests for its XT-8 system, and is developing new tests for its XT-8 system, the Company does not operate its business in operating segments. The Company determined, in accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 280, Segment Reporting, that it operates as one operating segment. The Company s Chief Operating Decision Maker (CODM) is its Chief

Table of Contents

Executive Officer and he reviews revenue at the business group level and manufacturing, operating income and expenses, and net income at the Company wide level to allocate resources and assess the Company s overall performance. The Company s business shares a centralized support function, including finance, human resources, legal, and corporate marketing, all of which report directly to the CODM. Accordingly, decisions regarding the Company s overall operating performance and allocation of Company resources are assessed on a consolidated basis.

Table of Contents

Recent Accounting Pronouncements

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

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

In February 2013, the FASB issued ASU 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* The amendment of this update requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. GAAP to be reclassified in its entirety to net income. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP that provide additional detail about those amounts. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. This guidance is effective for interim and annual periods beginning after December 15, 2012, and is to be applied prospectively. The adoption of this standard did not have a material impact for the Company in the first quarter of 2013.

Table of Contents

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on deposit with banks, money market instruments and certificates of deposit with original maturities of three months or less at the date of purchase.

Investments

Investments consist of debt securities in U.S. government-sponsored entities, corporate debt securities and commercial paper. Management classifies its investments as available-for-sale investments and recorded in the Condensed Consolidated Balance Sheets at fair value. Unrealized gains or losses for available-for-sale securities are included in accumulated other comprehensive income or loss, a component of stockholders equity. These available-for-sale investments are primarily held in the custody of a major financial institution. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

Other-than-Temporary Impairments on Investments

When the fair value of a debt security is less than its amortized cost, it is deemed impaired, and the Company will assess whether the impairment is other than temporary. An impairment is considered other than temporary if (i) the Company has the intent to sell the security, (ii) it is more likely than not that the Company will be required to sell the security before recovery of the entire amortized cost basis, or (iii) the Company does not expect to recover the entire amortized cost basis of the security. If impairment is considered other than temporary based on condition (i) or (ii) described earlier, the entire difference between the amortized cost and the fair value of the debt security is recognized in earnings. If an impairment is considered other than temporary based on condition (iii), the amount representing credit losses (defined as the difference between the present value of the cash flows expected to be collected and the amortized cost basis of the debt security) will be recognized in earnings, and the amount relating to all other factors will be recognized in other comprehensive income or loss.

The Company recognizes an impairment charge on publicly traded equity securities when a decline in the fair value of a security below the respective cost basis is judged to be other than temporary. The Company considers various factors in determining whether a decline in the fair value of these investments is other than temporary, including the length of time and extent to which the fair value of the security has been less than the Company s cost basis, the financial condition and near-term prospects of the issuer, and the Company s intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Investments in privately held companies are included in other assets in the Condensed Consolidated Balance Sheets and are primarily accounted for using the cost method. The Company monitors these investments for impairments and makes appropriate reductions in carrying values if the Company determines that an impairment charge is required based primarily on the financial condition and near-term prospects of these companies.

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and includes $1,094,000 at March 31, 2013 held as security for the Company s term loan and letter of credit with First PacTrust Bankcorp.

Receivables

Accounts receivable consist of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. The allowance for doubtful accounts is determined based upon specific identification of accounts at risk plus a general reserve for unknown items based upon the Company s historical experience.

Concentration of Risk

The Company had sales to one customer representing approximately 62% of total revenues for the three months ended March 31, 2013. Also, the Company s XT-8 system is manufactured by a limited number of suppliers that specialize in contract design and manufacturing of electronic and electromechanical devices for medical use.

Table of Contents

Product Shipment Costs

Product shipment costs are included in cost of sales in the accompanying Condensed Consolidated Statements of Comprehensive Loss. Shipping and handling costs were approximately $97,000 and $38,000 for the three months ended March 31, 2013 and 2012, respectively.

Product Warranties

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

Intangible Assets

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, including intangible assets, by periodically evaluating the carrying value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If impairment is indicated, the Company writes down the carrying value of the asset to its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows. The Company did not recognize any impairment charges for either of the three months ended March 31, 2013 or 2012.

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. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable.

Property and Equipment, net

Property, equipment and leasehold improvements are recorded at cost and depreciated using the straight-line method over the assets estimated useful lives, which are noted below.

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

Repair and maintenance costs are expensed as incurred.

Income Taxes

Our income tax expense, deferred tax assets and liabilities and reserves for unrecognized tax benefits reflect management s best assessment of estimated future taxes to be paid. We are currently subject to income taxes only in the United States but have been subject to income taxes in both the United States and the United Kingdom in previous years. Significant judgments and estimates are required in determining our consolidated income tax expense.

10

Table of Contents

We believe that it is more likely than not that the benefit from our deferred tax assets will not be realized. In recognition of this risk, we have provided a full valuation allowance on the net deferred tax assets relating to our net operating loss carryforwards and other deferred tax assets. If our assumptions change and we determine that we will be able to realize our deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on deferred tax assets at March 31, 2013 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.

Corporate Reorganization

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

2. Share-Based Compensation

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

The estimated fair value of options granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a straight-line basis to reflect vesting as it occurs. The share-based compensation expense is recorded in costs of sales, sales and marketing, research and development and general and administrative expenses based on the employee s respective function. The expense is derived from the Black-Scholes Option Pricing Model that uses several judgment-based variables to calculate the expense. The inputs include the expected term of the option or warrant, the expected volatility and other factors.

Expected Volatility. Expected volatility represents the volatility in the Company s stock price expected over the expected term of the option and is determined by review of the Company s and similar companies historical experience.

Expected Dividend. The Black-Scholes Option Pricing Model calls for a single expected dividend yield as an input. The Company assumed no dividends as it has never paid dividends and has no current plans to do so.

Risk-Free Interest Rate. The risk-free interest rate used in the Black-Scholes Option Pricing Model is based on published U.S. Treasury rates in effect at the time of grant for periods corresponding with the expected term of the option.

The compensation expense related to the grant of a restricted stock award or unit is calculated as the difference between the fair market value of the stock on the date of grant, less the cost to acquire the shares, as further adjusted to reflect a forfeiture rate.

Employee participation in the 2010 Equity Compensation Plan, or the 2010 Plan, is at the discretion of the Compensation Committee of the Board of Directors of the Company. All options granted under the 2010 Plan are exercisable at a price equal to the closing quoted market price of the Company s shares on the NASDAQ Global Market on the date of grant and generally vest over a period of between one and four years.

Options are generally exercisable for a period up to 10 years after grant and are forfeited if employment is terminated before the options vest. As of March 31, 2013, there were 287,487 shares available for future grant of awards under the 2010 Plan. Grants of stock options, restricted stock

awards and restricted stock units reduce the number of shares available for grant under the 2010 Plan.

Table of Contents

The following table summarizes stock option activity during the three month period ended March 31, 2013:

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2012	1,538,713	$ 5.42
Granted	399,600	$ 10.96
Exercised	(25,258)	$ 4.47
Cancelled	(25,041)	$ 5.17
Outstanding at March 31, 2013	1,888,014	$ 6.61
Exercisable at March 31, 2013	854,209	$ 5.61

During the three month period ended March 31, 2013, the Company granted an aggregate of 399,600 stock options, which had a weighted average exercise price of $10.96. The weighted average fair value of options granted during the three months ended March 31, 2013 was $7.13. Options that are exercisable as of March 31, 2013 have a remaining weighted average contractual term of 7.34 years, and an aggregate intrinsic value of $6,245,777. As of March 31, 2013, there were 1,888,014 options outstanding, which had a remaining weighted average contractual term of 8.28 years and an aggregate intrinsic value of $11,926,644.

Valuation of Share-Based Awards In accordance with *ASC* Topic 718, Stock Compensation, the Company evaluates the option award assumptions used in the Black-Scholes Option Pricing Model at each grant date using a consistent methodology for computing expected volatility, expected term and risk-free rate of return. Calculation of expected volatility is based on historical volatility, along with a comparison of comparable volatility in the Company s industry. The expected term is calculated using the vesting period of the award using the simplified method. The estimate of the risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company has never paid cash dividends and does not currently intend to pay cash dividends, and thus has assumed a 0% dividend yield. The assumptions used are summarized in the following table as of March 31, 2013:

Expected volatility (%)	74.00
Expected life (years)	6.08
Risk free rate (%)	1.08
Expected dividend yield (%)	
Estimated forfeitures (%)	10.00

The Company s restricted stock award and restricted stock units activity for the quarter ended March 31, 2013 is as follows:

	Restricted Stock Award		Restricted Stock Units	
	Number of shares	Weighted average Grant Date Fair Value	Number of Shares	Weighted average Grant Date Fair Value
Non-vested at December 31, 2012	965,710	$ 4.68		
Granted	9,775	$ 10.99	349,867	$ 10.89
Vested	(147,221)	$ 4.52		
Cancelled or expired	(31,212)	$ 5.87		
Non-vested at March 31, 2013	797,052	$ 4.75		

As of March 31, 2013, there was $2,876,674 of unrecognized compensation cost related to restricted stock awards. That cost is expected to be recognized over a weighted average period of 1.33 years. The total fair value of restricted stock awards that vested during the three month period ended March 31, 2013 and 2012 was $147,221 and $168,000, respectively. As of March 31, 2013, there was $2,654,585 of unrecognized compensation cost related to restricted stock units. That cost is expected to be recognized over a weighted average period of 1.83 years. No restricted stock units vested during the three month period ended March 31, 2013.

Restricted stock awards may be granted at the discretion of the Compensation Committee of the Board of Directors under the 2010 Plan in connection with the hiring or retention of personnel and are subject to certain conditions. Restrictions expire at certain dates after the grant date in accordance with specific provisions in the applicable agreement. During the three month period ended March 31, 2013, the Company awarded 9,775 shares of restricted stock, which had a fair value at the date of grant ranging from $10.31 to $11.19 per share. During the three month period ended March 31, 2013 and 2012, restricted stock compensation was charged to expense over the restriction period and amounted to $384,000 and $181,000, respectively.

There were no share-based compensation costs capitalized into assets as of March 31, 2013.

Table of Contents

3. Net Loss per Common Share

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

The computations of diluted net loss per share for the three months ended March 31, 2013 and 2012 did not include the effects of the following options and warrants to acquire stock and restricted stock awards which were outstanding as of the end of each period as the inclusion of these securities would have been anti-dilutive (in thousands).

	March 31,	
	2013	2012
Share options	1,888	1,702
Warrants		88
Restricted Stock-unvested, issued and held in escrow	797	1,027
Total	2,685	2,817

4. Inventories

Inventory on hand as of March 31, 2013 and December 31, 2012 was comprised of the following (in thousands):

	March 31, 2013	December 31, 2012
Raw materials	$ 1,014	$ 516
Work-in-process	1,416	925
Finished goods	745	552
Total	$ 3,175	$ 1,993

5. Property and Equipment, net

Property and equipment was comprised of the following as of March 31, 2013 and December 31, 2012 (in thousands):

	March 31, 2013	December 31, 2012
Property and equipment at cost:		
Plant and machinery	$ 3,223	$ 3,059
Instruments	6,105	5,795
Office equipment	1,140	1,047
Leasehold improvements	3,085	2,973
Total property and equipment at cost	13,553	12,874
Less accumulated depreciation	(6,206)	(5,800)
Property and equipment, net	$ 7,347	$ 7,074

Depreciation expense was $416,000 and $224,000 for the three months ended March 31, 2013 and 2012, respectively.

Table of Contents

6. Intangible assets, net

Intangible assets as of March 31, 2013 and December 31, 2012, respectively, comprise the following (in thousands):

	March 31, 2013			December 31, 2012		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$ 3,942	$ (1,376)	$ 2,566	$ 3,144	$ (1,312)	$ 1,832

Licenses have a weighted average remaining amortization period of 6.47 years as of March 31, 2013. Amortization expense for intangible assets amounted to $64,000 and $40,000 for the three months ended March 31, 2013 and 2012, respectively. Estimated future amortization expense for these licenses (assuming no impairment charges) is as follows (in thousands):

Years Ending March 31,	Amount
2014	$ 311
2015	311
2016	311
2017	306
2018	302
Thereafter	1,025
Total	$ 2,566

7. Loan payable

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to which the Company obtained a credit facility consisting of a revolving line of credit in the amount of up to $2.0 million and an equipment term loan in the amount of up to $2.0 million. In March 2011, the Company amended the loan and security agreement to increase the line of credit to $3.0 million and subsequently extended the original maturity date to July 2013.

In September 2012, the Company terminated the Square 1 Bank loan and security agreement and entered into a new term loan with First PacTrust Bancorp, consisting of the following two loans which were secured with $1,094,000 of restricted cash at March 31, 2013.

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

2) The Company obtained a variable rate term loan from First PacTrust Bankcorp in the amount of $836,000 with an initial interest rate of 3.75% that expires in July 2013. This term loan replaced the Square 1 equipment loan of the same amount with an interest rate of 6.75%. At March 31, 2013, the outstanding balance on the term loan was $335,000.

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

8. Leases

The Company has operating lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged were $199,000 and $282,000 for the three months ended March 31, 2013 and 2012, respectively. Pursuant to the Company s lease agreements, a portion of the monthly rental has been deferred. The balance deferred at March 31, 2013 was $1,799,000 and at December 31, 2012 was $1,359,000. During the three months ended March 31, 2013, the future minimum lease payments required over the next five years are as follows (in thousands):

Table of Contents

Years Ending March 31	Amount
2014	$ 1,030
2015	1,060
2016	1,092
2017	1,118
2018	1,131
Thereafter	3,914
Total future minimum payments	9,345
Less amounts representing interest	(16)
Net carrying value of lease payable	9,329
Less current portion	(1,030)
Non-current portion	$ 8,299

9. Fair Value of Financial Instruments

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

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

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

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

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

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company subject to *ASC Topic 820, Fair Value Measurements and Disclosures*, and the valuation approach applied to each class of financial instruments at March 31, 2013 and December 31, 2012, (in thousands):

	March 31, 2013			
	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs (Level 3)	Total

	for Identical Assets (Level 1)	(Level 2)		
Assets:				
Money market funds (cash equivalents)	$ 8,169	$	$	$ 8,169
Corporate notes and bonds		7,182		7,182
U.S. government and agency securities		3,805		3,805
Commercial paper		799		799
Preferred securities			1,000	1,000
Total assets measured at fair value	$ 8,169	$ 11,786	$ 1,000	$ 20,955

Table of Contents

	December 31, 2012			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents	$ 20,005	$	$	$ 20,005
Certificates of deposit		25,006		25,006
Preferred securities			1,000	1,000
Total assets measured at fair value	$ 20,005	$ 25,006	$ 1,000	$ 46,011

Level 2 available-for-sale securities are priced using quoted market prices for similar instruments or nonbinding market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs. The fair value measurement of the investments of preferred securities in a privately held company was classified as level 3 because significant unobservable inputs were used in the valuation due to the absence of quoted market prices. Significant unobservable inputs, which include financial condition and near-term prospects of the investees, recent financing activities of the investees, and the investees capital structure as well as other economic variables, reflected the assumptions market participants would use in pricing these assets. There were no significant transfers between levels during the three month period ended March 31, 2013.

The following table reconciles the beginning and ending balances of financial instruments that are remeasured on a recurring basis using significant unobservable inputs (Level 3) as of March 31, 2013 (in thousands):

	Preferred Securities
Beginning balance, January 1, 2013	$ 1,000
Total gains:	
Included in earnings	
Purchases, issuances, or settlements	
Ending balance, March 31, 2013	1,000

10. Investments

The following tables summarize the Company s available-for-sale investments (in thousands) based on the maturity date of the securities:

March 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term securities:				
Corporate notes and bonds	$ 1,562	$	$	$ 1,562
U.S. Government and agency securities	2,511		(1)	2,510
Commercial paper	799			799
	4,872		$ (1)	4,871
Long-term securities:				

Corporate notes and bonds	5,622	1	(4)	5,619
U.S. Government and agency securities	1,296			1,296
	6,918	1	(4)	6,915
Total	$ 11,790	$ 1	$ (5)	$ 11,786

The following table summarizes the maturities of the Company s available-for-sale securities at March 31, 2013:

(in thousands)	Amortized Cost	Fair Value
Less than 1 year	$ 4,872	$ 4,871
Due in 1 to 2 years	6,918	6,915
Total	**$ 11,790**	**$ 11,786**

11. Income taxes

The Company uses an estimated annual effective tax rate, which is based on expected annual income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates, to determine its quarterly provision for income taxes. Certain significant or unusual items are separately recognized in the quarter in which they occur and can be a source of variability in the effective tax rates from quarter to quarter.

As of March 31, 2013, the Company has recorded a full valuation allowance against all of its net deferred tax assets due to the uncertainty surrounding the Company s ability to utilize these assets in the future. Provision for income tax was $7,000 and $32,000 for the three months ended March 31, 2013 and 2012, respectively. Due to the Company s losses it only records tax provision or benefit related to minimum tax payments or refunds and interest related to its uncertain tax positions.

The total amount of unrecognized tax benefits was $382,000 as of March 31, 2013 which would impact the Company s effective tax rate if recognized. The gross liability for income taxes related to unrecognized tax benefits is included in other long-term liabilities in the Company s condensed consolidated balance sheets.

The total balance of accrued interest and penalties related to uncertain tax positions was $211,000 as of March 31, 2013. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company is subject to taxation in the U.S and in various state jurisdictions. In previous years, the Company was also subject to income taxes in the United Kingdom based upon its legacy operations. As of March 31, 2013, the Company s tax years after 2008 are subject to examination by the U.K. tax authorities. Except for net operating losses generated in prior years carrying forward to the current year, as of March 31, 2013, the Company is no longer subject to U.S. federal, state, or local examinations for years before 2007.

Table of Contents

ITEM 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report for the three months ended March 31, 2013, as well as the audited financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2012, included in our Annual Report on Form 10-K for the year ended December 31, 2012.

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as expect, anticipate, target, project, believe, goals, estimate potential, predict, may, will, might, could, intend, variations of these terms or the negative of those terms and similar expressions are i identify these forward-looking statements. Readers are cautioned that these forward-looking statements are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II of this report. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, as a Delaware corporation in February 2010. GenMark had no operations prior to its initial public offering, which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of: (i) the issuance of common stock of GenMark to the former shareholders of Osmetech; and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term Incentive awards and all warrants issued by Osmetech were exchanged for options and warrants exercisable for the common stock of the GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure.

Table of Contents

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 & Drug Administration, or the FDA, and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within approximately 30 minutes of receipt of an extracted and amplified nucleic acid sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports up to 24 independent test cartridges, each of which can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are hospitals and reference laboratories. As of March 31, 2013, we had an installed base of 339 analyzers, or placements, with our customers.

Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the three months ended March 31, 2013 and 2012 were approximately $4.2 million and $5.6 million, respectively. As of March 31, 2013, we had an accumulated deficit of $194.7 million. Our operations to date have been funded principally through cash from operations, borrowings, and sales of capital stock. We expect to incur increasing expenses over the next several years, principally to develop our NexGen system and additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

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

We are also developing our NexGen system. We are designing the NexGen system to integrate automated nucleic acid extraction and amplification with our eSensor® detection technology to enable technicians using the NexGen system to be able to place a raw or a minimally prepared patient sample directly into our test cartridge and obtain results without any additional steps. This sample-to-answer capability is enabled by the robust nature of our eSensor® detection technology, which is not impaired by sample impurities that we believe hinder competing technologies. We are designing our NexGen system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

Results of Operations Three months ended March 31, 2013 compared to the three months ended March 31, 2012

	March 31,			
(in thousands)	**2013**	**2012**	**$ Change**	**% Change**
Total revenue	$ 11,101	$ 2,159	$ 8,942	414%

Our product revenue consists primarily of revenue from the sale of reagents and test cartridges (consumables) with a small component due to our sale of instruments and other revenue. Consumable revenue for the quarter ended March 31, 2013 increased by $8,887,000, or 463% compared to the same quarter of 2012 due to higher reagent revenues of $10,806,000 versus $1,919,000 in the comparable period ended March 31, 2012. This increase in reagent revenue was primarily driven by a 79% increase in the number of our installed base of analyzers to 339 at March 31, 2013 from 189 as of March 31, 2012, along with an increase in consumable utilization per analyzer. Pricing changes were not a material cause of our significant increase in revenue. Our average annuity per analyzer increased from approximately $46,000 per analyzer per year at March 31, 2012 to about $146,000 per analyzer per year at March 31, 2013. The increase was not attributable to any one assay; however, our IVD (In Vitro Diagnostics) assay revenue in pharmacogenetics and infectious diseases increased significantly more than our other assay panels.

	March 31,			
(in thousands)	**2013**	**2012**	**$ Change**	**% Change**
Cost of sales	$ 5,034	$ 1,687	$ 3,347	198%
Gross profit	$ 6,067	$ 472	$ 5,595	1,185%

The increase in cost of sales for the quarter ended March 31, 2013 compared to the quarter ended March 31, 2012 was primarily related to the increase in consumable revenues in the current period. Increases in our cost of sales during the current quarter were primarily attributable to increased standard product costs of $2,923,000, $327,000 in royalties and $95,000 in instrument depreciation. We also incurred higher

headcount related costs of $492,000 to support manufacturing volumes, higher supplies and prototype expenses of $396,000 due to increased production and validation of new vendors, higher temporary labor expense of $157,000, higher facility and depreciation expenses $158,000 due to our expanded production infrastructure and new medical taxes of $129,000, all of which were offset by higher absorption due to production volume increase. The improvement to gross profit of $5,595,000 was primarily due to increased sales volumes and manufacturing efficiencies. We also continue to realize improved manufacturing efficiencies by driving process improvements related to larger batch sizes, which has resulted in substantially improved manufacturing yields.

Table of Contents

(in thousands)	March 31, 2013	2012	$ Change	% Change
Sales and marketing	$ 2,359	$ 1,418	$ 941	66%

The increase of $941,000 in sales and marketing expense for the three months ended March 31, 2013, compared to the three months ended March 31, 2012, was primarily driven by an increase in salary expense of $319,000, related sales commissions of $155,000 and consulting expense of $165,000, attributable to our increase in volume and our commitment to increase and improve our domestic commercial organization. The increase reflected the addition of approximately 10 headcount (three in marketing and seven in the sales force).

(in thousands)	March 31, 2013	2012	$ Change	% Change
General and administrative	$ 2,558	$ 2,587	$ (29)	-1%

General and administrative expense was $2,558,000 for the three months ended March 31, 2013 compared to $2,587,000 for the same period last year. The overall decrease of $29,000 was due to lower general and administrative facility spending of approximately $289,000, which was offset by an increase of seven headcount representing $128,000, audit fees of $50,000, and consulting services to support our human resources activities of $79,000.

(in thousands)	March 31, 2013	2012	$ Change	% Change
Research and development	$ 5,381	$ 1,949	$ 3,432	176%

The increase in research and development expense of $3,432,000 for the three months ended March 31, 2013, compared to the three months ended March 31, 2012, was primarily due to an increase in costs associated with the development of our NexGen system of $2,680,000, and assay development of $756,000. Although clinical trial costs tend to fluctuate depending on the timing of assay approvals through the FDA, the increase in assay development is mainly due to an increase in overall headcount of thirteen employees.

(in thousands)	March 31, 2013	2012	$ Change	% Change
Total other (expense) income	$ 63	$ (44)	$ (107)	243%

Other expense represents non-operating revenue and expenses, earnings on cash and cash equivalents, restricted cash, marketable securities, interest expense related to debt, and capital leases. The change in other income (expense) for the three months ended March 31, 2013, compared to the three months ended March 31, 2012, was due primarily to an increase in interest income earned of $67,000 on marketable securities, lower interest expense paid from our term loan and capital lease of $21,000 and other income of $20,000.

(in thousands)	March 31, 2013	2012	$ Change	% Change
Provision for income taxes	$ 7	$ 32	$ (25)	78%

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

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock, borrowings and gross margin generated from revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At March 31, 2013, we had $44,842,000 of working capital, including $32,018,000 in cash and cash equivalents.

Cash Flows

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

Three months ended:	March 31,	
(in thousands)	**2013**	**2012**
Cash used in operating activities	$ (6,104)	$ (5,496)
Cash (used in) provided by investing activities	(12,947)	4,244
Cash used in financing activities	(182)	(267)
Net decrease in cash and cash equivalents	$ (19,233)	$ (1,519)

Table of Contents

Cash flows used in operating activities

Net cash used in operating activities increased $608,000 to $6,104,000 for the three months ended March 31, 2013 compared to $5,496,000 for the three months ended March 31, 2012. The increased use of cash during the first quarter of 2013 was due primarily to an increase in inventory of $1,248,000 and accounts receivable of $1,143,000, offset by a lower loss of $1,383,000 and combination of other operating activities.

Cash flows (used in) provided by investing activities

Net cash used in investing activities increased by $17,190,000 to $12,947,000 for the three months ended March 31, 2013, compared to net cash provided by investing activities of $4,244,000 in the three months ended March 31, 2012. During the first quarter of 2013, we invested $13,848,000 in investments, primarily consisting of corporate debt securities and U. S. government securities. In addition, we continued to purchase equipment of $986,000 and our proceeds from sales and maturities of marketable securities decreased by $3,000,000.

Cash flows used in financing activities

Net cash used in financing activities decreased by $85,000 to $182,000 for the three months ended March 31, 2013, compared to cash used in financing activities of $267,000 for the three months ended March 31, 2012. During the first quarter of 2013, we received proceeds from stock exercises of $105,000.

In March 2010, we entered into a loan and security agreement with Square 1 Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $2.0 million and an equipment term loan in the amount of up to $2.0 million. In March 2011, we amended the loan and security agreement to increase the line of credit to $3.0 million and subsequently extended the original maturity date to July 2013.

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

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

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

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

We have prepared cash flow forecasts which indicate, based on our current cash resources available, that we will have sufficient resources to fund our business for at least the next 12 months. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, and expand our research and development, commercialization and manufacturing activities. Although we believe, based on our current business plan, that we have sufficient capital to reach a positive cash flow position, the amount of additional capital we may need to raise in the future depends on many factors, including:

the level of revenues and the rate of our revenue growth;

the level of expenses required to expand our commercial (sales and marketing) activities;

the level of research and development investment required to maintain our XT-8 system and develop our NexGen system and related test menus;

our need to acquire or license complementary technologies;

the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

Table of Contents

competing technological and market developments; and

changes in regulatory policies or laws that affect our operations.

We cannot be certain that additional capital will be available when needed or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in diagnostics companies or in the marketplace in general is limited due to then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire, on acceptable terms, or at all. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain additional debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, valuation of intangibles and other long-term assets, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and there have been no material changes to such policies or estimates during the three months ended March 31, 2013.

Contractual Obligations

We did not enter into any material contractual obligations during the three months ended March 31, 2013. We have no material contractual obligations that are not fully recorded on our consolidated balance sheets or fully disclosed in the Notes to Consolidated Financial Statements included elsewhere in this Quarterly Report.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, except that we have provided a $758,000 standby letter of credit as security for future rent to our landlord in connection the lease of our Carlsbad, California facility, as discussed in greater detail above.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no changes in our market risks during the quarter ended March 31, 2013.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of less than three months, and short-term investments, which have maturities of less than one year. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may in the future maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and short-term investments, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Interest Rate Risk

As of March 31, 2013, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

Table of Contents

Foreign Currency Exchange Risks

All of our operating facilities are located within the United States. We are a U.S. entity and our functional currency is the U.S. dollar. Virtually all of our revenues are based in the United States. In 2010, we entered into a license agreement that requires payment in Euros. We currently have no material operations outside of the United States, which significantly diminishes the extent of any foreign currency exchange risk we face.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports we file under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of the end of the period we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of March 31, 2013, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting that occurred in the quarterly period covered by this report that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are from time to time subject to various claims and legal actions in the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below and all of the other information set forth in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations, in evaluating our business and prospects. If any of the risks 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.

We have marked with an asterisk (*) those risks described below that reflect new risks or substantive changes from the risks described under Part I, Item 1A Risk Factors included in our Annual Report on Form 10-K for the year ended December 31, 2012.

We may not be successful in developing our NexGen system and its related test menu.*

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

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

We believe we have made significant progress in the development of our NexGen system and continue to remain highly focused on developing a multiplex, sample-to-answer diagnostic solution of the highest quality for our customers. As part of our ongoing development efforts, we recently prepared an assessment of the program in coordination with our development partners. Based on this assessment, we currently believe that the completion of development of our NexGen system will occur in the second quarter of 2014. However, our current estimate is based on a number of assumptions which could prove to be inaccurate or we may experience unanticipated technical challenges or other delays. If we are unsuccessful in completing development of our NexGen system within our expected time frame, or at all, our business and future prospects may be adversely affected.

Table of Contents

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

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

Medical offices and many hospitals outsource their molecular diagnostic testing needs to national or regional reference laboratories. Our business success depends on our ability to convince these target laboratories and hospitals to perform these tests internally with our products if they have historically outsourced their testing needs, or to replace their current testing platforms with our system and its related test offerings.

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

- the relative convenience and ease of use of our diagnostic systems over competing products;
- the introduction of new technologies and competing products that may make our technologies and products a less attractive solution for our target customers;
- the breadth of our menu of available diagnostic tests relative to our competitors;
- our success in training reference and hospital-based laboratories in the proper use of our products;
- the acceptance in the medical community and key opinion leaders of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts;
- the uncertainty and changes in reimbursement policies and rates related to molecular diagnostics products; and
- general economic conditions.

Professional societies, government agencies, practice management groups, private health/science foundations and organizations involved in healthcare issues may publish guidelines, recommendations or studies to the healthcare and patient communities. Recommendations of government agencies or these other organizations may relate to such matters as usage, cost-effectiveness and use of related products. Organizations like these have in the past made recommendations about our competitors products, such as the need for less frequent screening tests, which could result in reduced product sales. Moreover, the perception by the investment community or stockholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect the prevailing market price for our common stock.

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

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

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

cost effective; and

neither experimental nor investigational.

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

Table of Contents

Obtaining coverage and reimbursement approval for a product from each government or third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our product to each government or third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. For example, Medicare and Medicaid generally do not reimburse providers who use our Warfarin Sensitivity Test. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs. Further, third-party payors may choose to reimburse our customers per test based on individual biomarker detection, rather than on the basis of the number of results given by the test. This may result in reference laboratories, public health institutions and hospitals electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, these entities may purchase separate tests for each disease, rather than products, such as ours, that can be used to return multiple test results.

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

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

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

In addition, since January 2013, many Medicare contractors and private health insurers have not paid clinical laboratories for molecular diagnostic test claims using the new molecular test CPT codes. As a result, many clinical laboratories, including some of our customers, have received little or no reimbursement from Medicare for testing services since January 2013, and it remains unclear when these payments may be received, if at all. If Medicare does not process payments to our customers on a timely basis for past or future molecular testing services or our customers cannot support their businesses with cash flows from sources other than Medicare, our customers may significantly reduce the amount of additional product they purchase from us. The loss of any significant customer or a significant reduction in the amount of product ordered by any of our significant customers could adversely affect our revenue, results of operations and cash flows.

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

We have one large customer, Natural Molecular Testing Corporation, or NMTC, which accounted for approximately 62% of our total revenue for the three months ended March 31, 2013. While we have signed contracts with our significant customers, we may lose a significant customer if any existing contract with such customer expires without being extended, renewed, renegotiated or replaced or is terminated by the customer prior to expiration, to the extent such early termination is permitted by the applicable contract, or if the customer is unable to perform its obligations due to bankruptcy or other financial distress. Certain of our significant customers, including NMTC, are experiencing delays in receipt of reimbursements from Medicare, which has not paid many clinical laboratories on a regular basis for molecular diagnostic test claims coded to the new molecular test CPT codes since January 2013. If our significant customers do not receive timely or adequate reimbursement from Medicare for past or future molecular testing services, they may significantly reduce the amount of additional product they purchase from us. The loss of any significant customer or a significant reduction in the amount of product ordered by any of these customers could adversely

affect our revenue, results of operations and cash flows.

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. We obtained FDA clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We initially offered our XT-8 system and our Warfarin Sensitivity Test in July 2008, our Cystic Fibrosis Genotyping Test in July 2009, our Thrombophilia Risk Test in April 2010, and our Respiratory Viral Panel Test in September 2012. Our net losses were approximately $22.1 million and $24.0 million for the years ended December 31, 2012 and 2011, respectively. As of March 31, 2013, we had an accumulated deficit of $194.7 million. We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing operations, primarily related to our commercial organization (sales and marketing), research and development and regulatory activities, maintaining our existing intellectual property portfolio, obtaining additional intellectual property rights and investing in corporate infrastructure. Although we believe that we will become cash flow positive over the next few years, we cannot provide any assurance that we will achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our limited commercialization history and the rapidly evolving nature of our target market, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

Table of Contents

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

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

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

Although further and ongoing efforts will continue in 2013 and beyond to enhance our internal control over financial reporting, we believe that our remediation efforts now provide the foundation for compliance with the Committee of Sponsoring Organizations of the Treadway Commission (COSO) framework. As a result, our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012 no longer reported this material weakness or any other material weakness over financial reporting, and the audit report of our independent registered public accounting firm no longer expressed an adverse opinion on the effectiveness of our internal control over financial reporting as of December 31, 2012.

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

Disruptions in the supply of raw materials, consumable goods or other key product components, or issues associated with their quality from our single source suppliers, could result in a significant disruption in sales and profitability.

We must manufacture, or engage third parties to manufacture, components of our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. Our components are custom-made by only a few outside suppliers. In certain instances, we have a sole source supply for certain key product components. If we are unable to satisfy our forecasted demand from existing suppliers for our kits and are unable to find alternative suppliers at reasonably comparable prices, it could have a material adverse effect on our business, financial condition and results of operations. Additionally, we have entered into supply agreements with most of our suppliers of strategic reagents and parts to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. If our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable alternative on reasonable terms, or at all, which could limit our ability to manufacture our products.

In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on inventory levels, current market trends and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our products, there could be significant differences between our estimates and the actual amounts of products we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

Reliance on third-party manufacturers entails risk to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;

Table of Contents

possible breaches of manufacturing agreements by the third parties because of factors beyond our control;

possible regulatory violations or manufacturing problems experienced by our suppliers;

possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;

the potential obsolescence and/or inability of our suppliers to obtain required components;

the potential delays and expenses of seeking alternate sources of supply or manufacturing services;

the inability to qualify alternate sources without impacting performance claims of our products;

reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and

increases in prices of raw materials and key components.

The manufacturing operations for our test cartridges use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly to repair or replace and could require substantial lead time to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facility or the facilities of any of our suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, or otherwise, would limit our ability to meet customer demand for our XT-8 system and tests and would have a material adverse effect on our business, financial condition and results of operations. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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

We currently market our XT-8 instrument system and four FDA-cleared diagnostic tests. In addition, we have several diagnostic tests in the research, development or design stage. We have primarily placed our XT-8 systems with customers at no initial charge through reagent rental agreements, under which customers generally commit to purchase minimum quantities of test cartridges and reagents (consumables) over a typical period of one to three years, with a component of the cartridge and reagent price allocated to recover the instrument price. We also offer our XT-8 systems for sale. We expect sales of consumables associated with our XT-8 system will account for the vast majority of our revenues for at least the next several years. We intend to continue to dedicate a significant portion of our resources to the commercialization of our XT-8 system and its related test menu, while also dedicating significant resources to the development of our NexGen system and its related test menu. As a result, to the extent that our XT-8 system and our existing and future diagnostic and research products are not commercially successful or are withdrawn from the market for any reason, our operating results, financial condition and critical development programs would be harmed and we may be required to seek additional funding to support our ongoing operations.

In addition, we have limited marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on attracting customers for the XT-8 system and its related test menu and building brand loyalty. To successfully perform sales, marketing, distribution and customer support functions ourselves, we face a number of risks, including:

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

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

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

Some hospital-based and reference laboratories may not consider adopting our XT-8 system unless we offer a broader menu of diagnostic tests or may choose not to convert from competitive products unless and until we are able to offer a sample-to-answer instrument solution, such as our NexGen instrument. In addition, in order to commercialize our products, we are required to undertake time consuming and costly development activities, including clinical studies for which the outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to effectively compete with our XT-8 system and its related test menu, our revenues and our ability to achieve profitability will be significantly impaired.

Table of Contents

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

The markets for our technologies and products are highly competitive and we expect the intensity of competition to increase. We compete with many companies in the United States engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Categories of our competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, including Luminex Corporation; Nanosphere, Inc.; BioFire Diagnostics; Qiagen NV; Abbott Molecular Diagnostics, a division of Abbott Laboratories; and Hologic, Inc.;
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods, including Quest Diagnostics Incorporated and Laboratory Corporation of America; and
- companies that manufacture laboratory-based tests and analyzers, including Cepheid; Siemens; Hologic, Inc.; Qiagen NV; BioFire Diagnostics; Roche Diagnostics, a division of F. Hoffmann-La Roche Ltd.; and Abbott Molecular Diagnostics.

Our diagnostic tests also face competition from laboratory developed tests, or LDTs, developed by national and regional reference laboratories and hospitals. Such LDTs may not be subject to the same regulatory requirements, including those requiring clinical trials and FDA review and clearance or approval that may apply to our diagnostic products.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and our competitors improve their current products and expand their menu of diagnostic tests. Many of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, and more extensive manufacturing and distribution capabilities. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers and prospective customers needs on a timely basis. If we fail to effectively compete and keep pace with emerging technologies, our systems and related tests will become uncompetitive and our market share will decline, which would harm our business, financial condition and results of operations.

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

We are investing in the research and development of our NexGen instrument and related diagnostic tests to expand our future product offerings. Our diagnostic products are subject to 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental regulations, directives and/or entities prior to their marketing outside the United States. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510(k) clearance, pre-market approval or foreign regulatory approvals.

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

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

Table of Contents

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

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

Legislative or regulatory healthcare reforms may have a material adverse effect on our business and results of operations.

Federal and state governments in the United States are also undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. While the PPACA involves expanding coverage to more individuals, it includes new regulatory mandates and other measures designed to constrain medical costs. Among other requirements, the PPACA imposes a 2.3% excise tax on sales of medical devices by manufacturers that is expected to cost the medical device industry up to $20 billion over the next decade. Taxable devices include any medical device defined in Section 201(h) of the FDCA and intended for use by humans, with limited exclusions for devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we began paying the tax in 2013. Complying with PPACA could significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

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

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

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

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

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. From time to time we may become engaged in litigation with third parties having patent or other

intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. If a third party claims that we or any collaborator infringes its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;
- a court prohibiting us from selling or licensing our product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

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

Our commercial success is dependent in part on obtaining, maintaining and enforcing intellectual property rights, including patents. If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that compete with our products. Currently, our patent portfolio is comprised, on a worldwide basis, of over 150 issued U.S. and foreign patents and numerous pending applications. In general, patents have a term of 20 years from the application filing date or earlier claimed priority date. A majority of our issued and exclusively licensed patents will expire between 2013 and 2021, with approximately one half of the patents expiring by 2018. Several of our pending applications have the potential to mature into patents that might expire between 2028 and 2033. However, patents may not be issued based on any pending or future patent applications owned by or licensed to us and, moreover, issued patents owned or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

We have also licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate

sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we fail to comply with our material obligations under any of our patent license agreements, the licenses may be terminated and we could lose license rights that are important to our business. Furthermore, additional licenses we may need may not be available to us on commercially reasonable terms, or at all, which could adversely affect our results of operations and growth prospects.

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the PTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011 the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that have transitioned the United States from a first-to-invent system to a first inventor to file system and altered some of the processes for challenging issued patents. These changes may

Table of Contents

materially affect the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and patents of our collaborators and licensors. The patent situation in the medical device and diagnostic fields outside the United States is even more uncertain.

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

We also rely on trade-secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. We have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non-disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

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

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

If we are unable to retain key members of our senior management and scientists or hire additional skilled employees, we may be unable to achieve our goals.

Our performance is substantially dependent on the performance of our senior management. Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. Our senior managers can terminate their relationship with us at any time. The loss of services of any of these key personnel could significantly reduce our operational effectiveness and investor confidence and our stock price could decline. We do not maintain key-man life insurance on any of our employees.

In addition, our product development and marketing efforts could be delayed or curtailed if we are unable to attract, train and retain highly skilled technical employees and scientific advisors. To expand our research, product development and sales efforts, we will need to retain additional people skilled in areas such as electrochemical and molecular science, information technology, manufacturing, sales, marketing and technical support. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology. We may not be successful in hiring or retaining qualified personnel, and any failure to do so could have a material adverse effect on our business, financial condition and results of operations.

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

Demand for our Respiratory Viral Panel Test can be seasonal based upon influenza outbreaks. Also, unanticipated changes in customer demand for our products may result in constraints or inefficiencies related to our manufacturing, sales force, implementation resources and administrative infrastructure. These constraints or inefficiencies may adversely affect us as a result of delays, lost potential product sales or loss of current or

potential customers due to their dissatisfaction. Similarly, over-expansion or investments in anticipation of growth that does not materialize, or develops more slowly than we expect, could harm our financial results and result in overcapacity.

Table of Contents

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

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

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

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

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

Our manufacturing processes and facilities, and those of some of our contract manufacturers, must comply with the federal Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic announced and/or unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies.

We must also file reports of device corrections and removals and adhere to the FDA s rules on labeling and promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our contract manufacturers to take satisfactory corrective action in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our products;
- total or partial suspension of production or distribution;

withdrawal or suspension of marketing clearances or approvals;

clinical holds;

warning letters;

refusal to permit the import or export of our products; and

criminal prosecution.

Any of these actions, in combination or alone, could prevent us from marketing, distributing or selling our products and would likely harm our business.

Table of Contents

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our shares of common stock to decline and expose us to product liability or other claims, including contractual claims from parties to whom we sold products, and harm our reputation with customers. A recall involving our XT-8 system or our diagnostic tests would be particularly harmful to our business and financial results.

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, quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories from using some or all of our diagnostic products.

If our products do not perform as expected or the reliability of the technology on which our products are based is questioned, our operating results and business would suffer.

Our success depends on the market s confidence that we can provide reliable, high quality diagnostic products. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. As a result, our reputation and the public image of our products or technologies will be significantly impaired if our products fail to perform as expected. Although our diagnostic systems are designed to be user friendly, the functions they perform are complex and our products may develop or contain undetected defects or errors.

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

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

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

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

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to develop, and conduct clinical studies and obtain regulatory clearances for, additional diagnostic tests;
- the expenses we incur for research and development required to maintain and improve our technology, including developing our NexGen system;

the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;

the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution expenses;

the expenses we incur in licensing biomarkers from third parties to expand the menu of diagnostics tests we plan to offer;

Table of Contents

- our sales strategy and whether the revenues from sales of our test cartridges or XT-8 system will be sufficient to offset our expenses;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our XT-8 system and its related test menu. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a shortfall in demand for our products could have an immediate and material impact on our business and financial condition.

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

As a public company listed in the United States, we incur significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Global Market, may increase our legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If we nevertheless fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Current economic conditions and the uncertain economic outlook may adversely impact our business, results of operations, financial condition or liquidity.

Global economic conditions may remain challenging and uncertain for the foreseeable future. These conditions not only limit our access to capital but also make it extremely difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign businesses and consumers to slow spending on our products and services, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government s allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers, increase our allowance for doubtful accounts and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments and such losses have historically been within our expectations and the provisions established, we may not continue to experience the same loss rates that we have in the past, especially given the current turmoil of the worldwide economy. Additionally, these economic conditions and market turbulence may also impact our suppliers causing them to be unable to supply in a timely manner sufficient quantities of customized components, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

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

The majority of our XT-8 systems are provided to customers via reagent rental agreements, under which customers are afforded the right to use the XT-8 system in return for a commitment to purchase minimum quantities of reagents and test cartridges over a period of time. Accordingly, we must either incur the expense of manufacturing XT-8 systems well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our XT-8 systems. The amount of capital required to provide these systems to customers depends on the number of systems placed. Our ability to generate capital to cover these costs depends on the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we continue not to sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected.

We use hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research, product development and manufacturing processes involve the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resulting injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Our operations are regulated and

Table of Contents

may require that environmental permits and approvals be issued by applicable government agencies. Compliance with environmental laws and regulations may be expensive and may impair our research, development and production efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

Our corporate structure may create tax inefficiencies.

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

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

As of December 31, 2012, we had net operating loss (NOL) carryforwards of approximately $121.2 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2032. Section 382 of the U.S. Internal Revenue Code, as amended, or the Code, generally imposes an annual limitation on the amount of NOL carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. We have determined that we have experienced multiple ownership changes under Section 382 of the Code. As of December 31, 2012, we estimated that approximately $63.7 million of U.S. federal net operating losses may be utilized in the future based on limitations that we have calculated under Section 382 of the Code. Our ability to use the current NOL carryforwards may also be limited by the issuance of common stock in the future. To the extent our use of NOL carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use NOL carryforwards. We have recorded a full valuation allowance against our deferred net assets.

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

We are exposed to risks associated with long-lived and intangible assets that may become impaired and result in an impairment charge.

The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. These events or changes might include an inability to successfully deliver an instrument to the marketplace and attain customer acceptance, a change in the rights or use of licensed intellectual property or other matters. Adverse events or changes in circumstances may affect the estimated discounted future cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Information technology systems implementation issues or security threats could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an enterprise resource planning software system. To more fully realize the potential of this system, we are continually reassessing and upgrading processes and this may be more expensive, time

consuming and resource intensive than planned. Any disruptions that may occur in the operation of this system or any future systems or any unauthorized access to our information systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows and to otherwise operate our business in a secure environment, all of which could adversely affect our financial results, stock price and reputation.

Table of Contents

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

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

The federal False Claims Act, or the FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. If our marketing, sales or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition and results of operations.

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

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

To the extent we commence commercial operations overseas, we will be subject to the U.S. Foreign Corrupt Practices Act, or the FCPA, and other countries anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and results of operations.

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

Assuming we receive the applicable regulatory approvals, we intend to market our diagnostic products outside the United States through third-party distributors. These distributors may not commit the necessary resources to market and sell our products to meet our expectations. If distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or if we are unable to locate distributors in particular geographic areas, our ability to realize revenue growth based on sales outside the United States would be harmed.

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

United States on a timely basis, if at all, which could harm our ability to expand into markets outside the United States.

Table of Contents

Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

In connection with our grant of restricted stock awards to employees, at the election of the recipient, the number of shares issued on the date that the restricted stock vests is net of the minimum statutory tax withholding requirements that we pay in cash to the appropriate taxing authorities on behalf of our employees. The following table sets forth information about repurchases of our common stock to cover employee income tax withholding obligations in connection with the vesting of restricted stock awards under our 2010 Equity Incentive Plan, or the 2010 Plan, for the three months ended March 31, 2013 (shares in thousands):

Period of Repurchase	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicity Announced Plan or Program
January 1, 2013 January 31, 2013	624	$ 10.26	
February 1, 2013 February 28, 2013	169	11.09	
March 1, 2013 March 31, 2013			
Total	793	$ 10.44	

Table of Contents

Use of Proceeds from Registered Securities

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.
None.

ITEM 4. MINE SAFETY DISCLOSURES.
None.

ITEM 5. OTHER INFORMATION.
None.

Table of Contents

ITEM 6. EXHIBITS.

The exhibits listed in the Exhibit Index are incorporated herein by reference.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GENMARK DIAGNOSTICS, INC.

Date: May 8, 2013

/s/ Richard B. Slansky
Richard B. Slansky
Chief Financial Officer
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Listed and indexed below are all Exhibits filed as part of this report.

3.1	Certificate of Incorporation (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
3.2	Bylaws (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the Commission on March 19, 2010).
10.1	Form of Restricted Stock Units Grant Notice and Agreement (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 12, 2013).
10.2	The GenMark Diagnostics, Inc. 2013 Bonus Plan (Incorporated by reference to our Current Report on Form 8-K filed with the Commission on March 12, 2013).
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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