

GenMark Diagnostics, Inc.
Form 10-Q
May 10, 2012
[Table of Contents](#)

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

FORM 10-Q

(Mark One)

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

March 31, 2012 For the quarterly period ended March 31, 2012

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)

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

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

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

Indicate by check mark 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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

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

The number of outstanding shares of the registrant's common stock on April 29, 2012 was 21,134,078.

PART I - FINANCIAL INFORMATION

(Unaudited)

Item 1.	<u>Financial Statements</u>	1
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	15
Item 4.	<u>Controls and Procedures</u>	16
	PART II - OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	18
Item 1A.	<u>Risk Factors</u>	18
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
Item 3.	<u>Defaults Upon Senior Securities</u>	18
Item 4.	<u>Safety Disclosures</u>	18
Item 5.	<u>Other Information</u>	18
Item 6.	<u>Exhibits</u>	18

Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****GENMARK DIAGNOSTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except par value)**

	December 31, 2011 As of March 31, 2012 (Unaudited)	December 31, 2011 As of December 31, 2011
Current assets		
Cash and cash equivalents	\$ 23,801	\$ 25,320
Short-term investments		5,000
Accounts receivable, net of allowance of \$70 and \$98 at March 31, 2012 and December 31, 2011, respectively	1,055	1,098
Inventories	2,094	2,168
Other current assets	135	322
Total current assets	27,085	33,908
Property and equipment, net	3,417	2,836
Intangible assets, net	1,722	1,362
Other long-term assets	102	80
Total assets	\$ 32,326	\$ 38,186
Current liabilities		
Accounts payable	\$ 1,698	\$ 1,201
Accrued compensation	1,107	1,521
Current portion of long-term debt	1,015	1,000
Other current liabilities	1,562	2,659
Total current liabilities	5,382	6,381
Long-term liabilities		
Long-term debt	410	583
Other non-current liabilities	726	588
Total liabilities	\$ 6,518	\$ 7,552
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued		
Common stock, \$0.0001 par value; 100,000 authorized; 21,137 and 20,478 issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	2	2
Additional paid-in capital	200,263	199,531
Accumulated deficit	(174,021)	(168,463)
Accumulated other comprehensive loss	(436)	(436)
Total stockholders' equity	25,808	30,634

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

Total liabilities and stockholders equity	\$	32,326	\$	38,186
--	-----------	---------------	-----------	---------------

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**GENMARK DIAGNOSTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(In thousands, except per share data)****(Unaudited)**

	Three Months Ended March 31,	
	2012	2011
Product Revenue	\$ 2,120	\$ 693
License and other revenue	39	65
Total revenue	2,159	758
Cost of sales	1,687	1,501
Gross profit (loss)	472	(743)
Operating expenses		
Research and development	1,949	2,564
Sales and marketing	1,418	1,219
General and administrative	2,587	2,123
Total operating expenses	5,954	5,906
Loss from operations	(5,482)	(6,649)
Other (expense) income, net	(44)	18
Loss before income taxes	(5,526)	(6,631)
Provision for income taxes	(32)	(11)
Net loss	\$ (5,558)	\$ (6,642)
Net loss per share, basic and diluted	\$ (0.28)	\$ (0.56)
Weighted average number of shares outstanding	20,094	11,771
Condensed consolidated statements of comprehensive loss for the three months ended March 31, 2012 and 2011		
Net loss	\$ (5,558)	\$ (6,642)
Foreign currency translation adjustment		
Comprehensive loss	\$ (5,558)	\$ (6,642)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents**GENMARK DIAGNOSTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(In thousands)****(Unaudited)**

	Three months Ended March 31,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (5,558)	\$ (6,642)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	264	289
Share-based compensation	506	475
Change in allowance for doubtful accounts	(28)	(48)
Provision for excess and obsolete inventory	(636)	(1)
Changes in operating assets and liabilities:		
Trade accounts receivable	72	(37)
Inventories	757	26
Other current assets	165	1,811
Accounts payable	(112)	668
Accrued compensation	(188)	(152)
Accrued and other liabilities	(738)	521
Net cash used in operating activities	(5,496)	(3,090)
Investing activities:		
Payments for intellectual property licenses	(739)	
Purchases of property and equipment	(17)	(185)
Proceeds of sale of investments	5,000	
Net cash provided by (used in) investing activities	4,244	(185)
Financing activities:		
Proceeds from borrowings		2,000
Principal repayment of long-term debt	(267)	
Net cash provided by (used in) financing activities	(267)	2,000
Net decrease in cash and cash equivalents	(1,519)	(1,275)
Cash and cash equivalents at beginning of period	25,320	18,329
Cash and cash equivalents at end of period	\$ 23,801	\$ 17,054
Supplementary schedule of non-cash transactions:		
Property and equipment purchased with capital lease	\$ 109	\$
Transfer of systems from property and equipment into inventory	47	
Property and equipment costs incurred but not paid included in accounts payable and other current liabilities	728	161

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

As the reorganization is 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 represents the difference between the nominal value of the shares issued by GenMark, and the total of the additional paid-in capital and nominal value of Osmetech's shares cancelled pursuant to the described reorganization; and
- (iv) the accumulated deficit represents the aggregate of the accumulated deficit of Osmetech and the Company.

Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, Long Term Incentive Awards and all warrants issued were exchanged for options and warrants exercisable for the common stock of the Company.

In these consolidated financial statements, the Company means Osmetech when referring to periods prior to the corporate reorganization and 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 \$174.0 million at March 31, 2012. Cash and cash equivalents at March 31, 2012 were \$23.8 million.

Management expects operating losses to continue through the foreseeable future until the Company has expanded its product offerings and increased its product revenues to an extent that covers 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 unutilized credit facilities, that the Company has sufficient capital to fund its operations for at least the next twelve months.

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for audited financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the three months ended March 31, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. The information presented in the condensed consolidated financial statements and related footnotes at March 31, 2012, and for the three months ended March 31, 2012 and 2011, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2011 have been derived from our audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in our annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 21, 2012.

Segment Information

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

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

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

Table of Contents

Recent Accounting Pronouncements

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

In May 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-04, Amendment to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs (ASU 2011-04), which amended Accounting Standards Codification (ASC) Topic 820, Fair Value Measurement. The objective of this guidance is to develop common requirements for measuring fair value and for disclosing information about fair value measurements in accordance with GAAP and International Financial Reporting Standards. The guidance further explains how to measure fair value, but does not require additional fair value measurements. ASU 2011-04 is to be applied prospectively for fiscal years and interim periods within those years beginning after December 15, 2011. The Company's adoption of this guidance effective January 1, 2012 resulted in no additional disclosures in the notes to the Company's condensed consolidated financial statements, but did not have a material quantitative effect.

Fair Value of Financial Instruments

Assets and liabilities are classified based upon the lowest level of input that is significant to the fair value measurement. The carrying amounts of financial instruments such as cash equivalents, accounts receivable, prepaid and other current assets, accounts payable and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company reviews the fair value hierarchy on a quarterly basis. Changes in the observations or valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The Company's cash equivalents and short-term investments include money market funds and certificates of deposit. When available, the Company uses quoted market prices to determine fair value and classify such items as Level 1. If quoted market prices are not available, prices are determined using prices for recently traded financial instruments with similar underlying terms, such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies such items as Level 2.

Cash and cash equivalents and short-term investments

Cash and cash equivalents consist of cash on deposit with banks, money market instruments and certificates of deposit with maturities of three months or less at the date of purchase. Short-term investments consist of a certificate of deposit that matures in greater than three months, but less than one year from the date of purchase. The carrying amounts reported in the balance sheets for cash, cash equivalents and short-term investments are stated at their fair market value.

Concentration of Risk

The Company had sales to one customer representing approximately 39% of total revenues for the three months ended March 31, 2012. 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.

Product Shipment Costs

Product shipment costs are included in sales and marketing expense in the accompanying Condensed Consolidated Statements of Operations and Comprehensive Loss. Shipping and handling costs were \$38,000 and \$28,000 for the three months ended March 31, 2012 and 2011, respectively.

Product Warranties

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

Impairment of Long-Lived Assets

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

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 undiscounted cash flows.

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:

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

Effective January 1, 2012, the Company changed its estimated useful life for instruments from three to four years and estimated useful life of office equipment from between two and four years to five years.

Property and equipment include diagnostic instruments used for sales demonstrations or placed with customers under several types of arrangements, including performance evaluation period programs (PEPs), and rentals. PEPs are placed with customers for evaluation periods of up to six months. The customer is required to purchase a minimum amount of reagents and at the end of the evaluation period must purchase, rent, or return the instrument. Maintenance and repair costs are expensed as incurred.

Income Taxes

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

Table of Contents

Corporate Reorganization

During the quarter ended June 30, 2011, the Company underwent a corporate reorganization (the "Reorganization") intended to simplify its U.S. entity structure. As part of the Reorganization, Osmetech Technologies, Inc. merged into Clinical Micro Sensors, Inc. ("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. It is anticipated that the Reorganization will not trigger any material U.S. federal or U.K. income tax expense. Additionally, 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, CMS and Osmetech, Inc.

2. Share-Based Compensation

The Company recognizes share-based compensation expense related to share options and restricted stock issued to employees, directors and consultants in exchange for services. The compensation expense is based on the fair value of the awards, which are determined by utilizing various assumptions regarding the underlying attributes of the options and shares. The estimated fair value of options granted and restricted stock, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a straight line basis over the period the vesting occurs. The share-based compensation expense is recorded in cost of sales, sales and marketing, research and development and general and administrative expenses based on the employee's or consultant's respective function. The option expense is derived from the Black-Scholes Option Pricing Model that uses several judgment based variables to calculate the expense. The inputs include the expected life of the option or warrant, the expected volatility and other factors. The compensation expense related to the restricted stock is calculated as the difference between the fair market value of the stock on the date of grant, less the cost to acquire the shares, which is \$0.0001 per share, and is recognized over the vesting period of the award.

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

Employee participation in the Plan is at the discretion of the compensation committee or senior management of the Company. All options granted since June 3, 2010 are exercisable at a price equal to the average closing quoted market price of the Company's shares on the NASDAQ on the date of grant. Options granted prior to June 3, 2010 under the Osmetech plc 2003 U.S. Equity Compensation Plan were exercisable at a price equal to the average closing quoted market price of the Osmetech plc's shares on the Alternative Investment Market of the London Stock Exchange on the date of the grant as adjusted for the exchange ratio to the Company's shares as described above. Options generally vest between 1 and 4 years.

Options are generally exercisable for a period up to 10 years after grant and are forfeited if the employee leaves the Company before the options vest. Employees generally have 90 days after leaving the Company to exercise vested options. As of March 31, 2012, there were no shares available for future grant of awards under the Plan. Restricted stock grants reduce the amount of stock options available for grant under the 2010 Plan and are excluded from the table below.

The following table summarizes stock option activity during the three months ended March 31, 2012. There was no warrant activity for the three months ended March 31, 2012.

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2011	1,598,894	\$ 5.38
Granted	169,517	\$ 4.31
Exercised		
Cancelled	(66,517)	\$ (5.05)
Outstanding at March 31, 2012	1,701,894	\$ 5.29

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

Exercisable at March 31, 2012

679,812

\$

6.12

As of March 31, 2012, there were 1,518,591 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.58 years, and an aggregate intrinsic value of \$30,745.

Valuation of Share-Based Awards The Black-Scholes option pricing model was used for estimating the grant date fair value of stock options granted during the three months ended March 31, 2012 with the following assumptions:

Expected volatility (%)	70.00
Expected life (years)	5.78
Risk free rate (%)	1.06
Expected dividend yield (%)	0.00
Estimated forfeitures (%)	10.00

Table of Contents

The Company's non-vested restricted share award (RSA) activity for the quarter ended March 31, 2012 is as follows:

Restricted Stock Awards	Number of shares	Weighted average Grant Date Fair Value
Non-vested at December 31, 2011	403,062	\$ 4.22
Granted	684,721	\$ 4.16
Vested	(40,419)	\$ (4.19)
Cancelled or expired	(20,537)	\$ (4.38)
Non-vested at March 31, 2012	1,026,827	\$ 4.18

As of March 31, 2012, there was \$3.3 million of unrecognized compensation cost related to RSAs. That cost is expected to be recognized over a weighted average-period of 3.39 years. The total fair value of restricted shares vested during the quarter ended March 31, 2012 and 2011 was \$168,000 and \$318,000, respectively.

RSAs may be granted at the discretion of the Board of Directors under the Equity Incentive 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 quarter ended March 31, 2012, the Company awarded 684,721 shares of restricted stock, which had a fair value at the date of grant ranging from \$4.14 to \$4.38 per share. During the quarter ended March 31, 2011, the Company awarded 130,800 shares of restricted stock, which had a fair value at the date of grant ranging from \$4.28 to \$4.50 per share. Compensation under these restricted stock awards is charged to expense over the restriction period and amounted to \$181,000 and \$218,000 for the three months ended March 31, 2012 and 2011, respectively.

There was no stock compensation costs capitalized into assets as of March 31, 2012.

Table of Contents**3. Net Loss per Common Share**

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

The computations of diluted net loss per share did not include the effects of the following securities as the inclusion of these items would have been anti-dilutive (in thousands):

	March 31,	
	2012	2011
Common stock options outstanding	1,702	1,315
Warrants	88	88
Restricted Stock unvested, issued and held in escrow	1,027	
Restricted Stock vested, not issued or outstanding		61
Total	2,817	1,464

Common Stock Warrants During 2009, the Company issued warrants to purchase 132,475 of Osmetech's ordinary shares with an exercise price of £4.60 per share, and warrants to purchase 88,317 of Osmetech's ordinary shares with an exercise price of £6.90 per share to a director for services to the Company in connection with the share offering completed in 2009. Pursuant to the terms of the warrant, the warrant to purchase 132,475 was cancelled upon the closing of the IPO in June 2010. At the same time, the warrant to purchase 88,317 of Osmetech's ordinary shares was converted to warrants to purchase 88,317 shares of the Company's common stock at an exercise price of \$9.98. These warrants were fully vested and exercisable upon issue, and shall continue to be exercisable up to and including the earlier to occur of (i) 60 days after the director leaving the Company's board of directors (for whatever reason) and (ii) June 30, 2012.

4. Inventory-net

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

	2012	2011
Raw materials	\$ 1,028	\$ 1,012
Work-in-process	564	706
Finished goods	502	450
	\$ 2,094	\$ 2,168

5. Property and Equipment, net

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

	March 31, 2012	December 31, 2011
Property and equipment at cost:		
Plant and machinery	\$ 2,623	\$ 2,539
Instruments	4,492	3,918

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

Office equipment	872	848
Leasehold improvements	593	583
 Total property and equipment at cost	 8,580	 7,888
Less accumulated depreciation	(5,163)	(5,052)
 Net property and equipment	 \$ 3,417	 \$ 2,836

Depreciation expense was \$224,000 and \$286,000 for the three months ended March 31, 2012 and 2011, respectively.

6. Intangible assets

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

	March 31, 2012			December 31, 2011		
	Gross		Net	Gross		Net
	carrying	Accumulated	carrying	carrying	Accumulated	carrying
	amount	amortization	amount	amount	amortization	amount
Licensed intellectual property	\$ 2,874	\$ (1,152)	\$ 1,722	\$ 2,474	\$ (1,112)	\$ 1,362

During the three months ended March 31, 2012, the Company acquired exclusive and non-exclusive licenses for various microfluidic technology for a license fee of \$400,000 which will be amortized over a 10 year period of expected use.

Licenses have a weighted average remaining amortization period of 8.8 years as of March 31, 2012. Amortization expense for intangible assets amounted to \$40,000 and \$3,000 for the three months ended March 31, 2012 and 2011, respectively. Estimated future amortization expense for these licenses (assuming no impairment charges) is as follows (in thousands):

Years Ending March 31,	
2013	\$ 199
2014	199
2015	199
2016	199
2017	195
Thereafter	731
Total	\$ 1,722

7. Loan payable

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to obtaining a credit facility consisting of a revolving line of credit in the amount of up to \$2 million and an equipment term loan in the amount of up to \$2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank's prime rate (3.25% as of March 31, 2012) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank's prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank's prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank's prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to \$3.0 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

Table of Contents

In March 2011, an additional loan was made available under the amended loan and security agreement for up to \$1.0 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank's prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank's prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of March 31, 2012, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had a balance of \$1.3 million used to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility on the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% were due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that were then outstanding are payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

Pursuant to the terms of the loan and security agreement, the Company is required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the loan and security agreement includes several restrictive covenants, including requirements that the Company obtains the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to the Company's property, making distributions to stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount the Company can borrow under the term loan to license genetic biomarkers to \$500,000. To secure the credit facility, the Company granted Square 1 Bank a first priority security interest in its assets and intellectual property rights. The Company is currently in compliance with all ratios and covenants.

8. Lease payable

In January 2012 the Company entered into a lease agreement for office furniture totaling \$136,000. Terms of the lease require an initial payment of \$15,500 and fifty nine payments of \$2,040 per month.

9. Fair Value of Financial Instruments

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

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

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

Certificates of deposit: The carrying amounts reported in the balance sheets for certificates of deposit that are reported as short-term investments are stated at their fair market value. Short-term investments are classified as Level 2.

Non-recurring measurements: The Company measures the fair value of its long-lived assets on a periodic basis when it appears that there may be requirement to do so, such as an indication of impairment.

The following table presents the Company's hierarchy for assets measured at fair value on a recurring basis as of March 31, 2012 and December 31, 2011 (in thousands):

Quoted Prices in Active	March 31, 2012		Total
	Significant Other Observable	Significant Unobservable Inputs (Level 3)	

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

	Markets for Identical Assets (Level 1)	Inputs (Level 2)	
Cash equivalents	\$ 18,234	\$	\$ 18,234

	December 31, 2011			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents	\$ 19,225	\$	\$	\$ 19,225
Certificates of deposit		5,000		5,000

10. 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, 2012, 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 \$32,000 and \$11,000 for the three months ended March 31, 2012 and 2011, 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, 2012 which would impact the 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 related to uncertain tax positions was \$133,000 as of March 31, 2012. The Company recognizes interest 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 twelve months.

The Company is subject to taxation in the U.S., the U.K. based on its legacy operations, and in various state jurisdictions. As of March 31, 2012 the Company's tax years after 2007 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, 2012, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2006.

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 Item 1 of this Quarterly Report for the three months ended March 31, 2012, 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, 2011, included in our Annual Report on Form 10-K for the year ended December 31, 2011. 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 we expect, anticipate, target, project, believe, goals, estimate, potential, predict, may, will, expect, might, could, intend, variations of these terms or the negative of those terms and similar expressions are intended to 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 I of our Annual Report on Form 10-K for the year ended December 31, 2011. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

GenMark was established to serve as the parent company of Osmetech upon a corporate reorganization in Delaware in February 2010 and had no operations prior to its initial public offering which was completed in June 2010. Immediately prior to the closing of the initial public offering, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of (i) the issuance of common stock of GenMark to the former shareholders of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech held shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization.

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the FDA and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within 30 minutes of receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports between one and three analyzers. Each analyzer holds up to eight independent test cartridges, resulting in the XT-8 system supporting up to 24 test cartridges, each of which can be run independently, resulting in a convenient and flexible workflow for our target customers, which are hospitals and reference laboratories. As of March 31, 2012, we had an installed base of 189 analyzers, or placements, with our customers.

We have developed six tests for use with our XT-8 system and expect to expand this test menu by introducing new tests annually. Three of our diagnostic tests have received FDA clearance, including our Cystic Fibrosis Genotyping Test, which detects pre-conception risks of cystic fibrosis, our Warfarin Sensitivity Test, which determines an individual's ability to metabolize the oral anticoagulant warfarin, and our Thrombophilia Risk Test, which detects an individual's increased risk of blood clots. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed a Respiratory Viral Panel Test, which detects the presence of major respiratory viruses and is currently labeled for Research Use Only (RUO). In December 2011, we submitted our Respiratory Viral Panel Test to the FDA for 510(k) clearance. We also have developed a Hepatitis C Virus genotyping assay and a 2C19 genotyping assay, versions of which are available for Research Use Only (RUO). We also have a pipeline of several additional potential products in different stages of development or design, including a diagnostic test for mutations in a gene known as KRAS, which is predictive of an individual's response rates to certain prescribed anti-cancer therapies, and other tests.

We are also developing our next-generation platform, the 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 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.

Table of Contents

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, 2012 and 2011 were approximately \$5.5 million and \$6.6 million, respectively. As of March 31, 2012, we had an accumulated deficit of \$174.0 million. Our operations to date have been funded principally through sales of capital stock, borrowings and revenues. 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.

Results of Operations Three months ended March 31, 2012 compared to the three months ended March 31, 2011 *(in thousands)***Revenue**

	March 31,		\$ Change	% Change
	2012	2011		
Three months ended	\$ 2,159	\$ 758	\$ 1,401	185%

The increase in revenue for the first quarter ended March 31, 2012 as compared to the first quarter of 2011 was due to higher reagent revenues of \$1.9 million versus \$608,000 in the comparable period. This increase in reagent revenue was driven by the increase in the number of our installed base of systems as well as our expanded menu of tests available for sale, including products at higher price points than legacy tests.

Cost of Sales and Gross Profit (Loss)

	March 31,		\$ Change	% Change
	2012	2011		
Cost of Sales-three months ended	\$ 1,687	\$ 1,501	\$ 186	12%
Gross Profit (Loss)-three months ended	\$ 472	\$ (743)	\$ 1,215	164%

The increase in cost of sales for the first quarter ended March 31, 2012 compared to the first quarter of 2011 was directly related to the increase in reagent sales. The improvement to a gross profit of \$472,000 and 22% of revenue versus a gross loss of \$743,000 and (98%) of revenue for the first quarter of 2011 was primarily due to two factors. First, the increase in volume allowed for increased absorption of our fixed manufacturing costs since we have unused manufacturing capacity which was put in place in anticipation of future growth. Second, we have realized better manufacturing efficiencies since relocating manufacturing operations from Pasadena, CA to Carlsbad, CA which resulted in substantially improved manufacturing yields.

Operating Expenses**Research and Development**

	March 31,		\$ Change	% Change
	2012	2011		
Three months ended	\$ 1,949	\$ 2,564	\$ (615)	(24)%

The decrease in research and development expense for first quarter ended March 31, 2012 compared to the first quarter of 2011 was primarily due to costs associated with the transition of research and development from Pasadena, CA to Carlsbad, CA in 2011 that did not recur in 2012, including severance-related costs as well as costs related to obtaining FDA certification of the Carlsbad facility, and lower clinical trial costs since there were no clinical trials in process during the first quarter of 2012.

Sales and Marketing

	March 31,		\$ Change	% Change
	2012	2011		

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

Three months ended	\$ 1,418	\$ 1,219	\$ 199	16%
--------------------	----------	----------	--------	-----

The increase in sales and marketing expense was primarily driven by an increase in sales commissions and other variable sales costs associated with the significant increase in revenue as well as increased headcount costs associated with growing our commercial team in anticipation of continued commercial initiatives and revenue growth.

Table of Contents***General and Administrative***

	March 31,			
	2012	2011	\$ Change	% Change
Three months ended	\$ 2,587	\$ 2,123	\$ 464	22%

The increase in general and administrative expense for the first quarter ended March 31, 2012 compared to the first quarter of 2011 was primarily due to increased headcount costs associated with building of the management team, including severance costs, and increased use of outside consulting and audit services associated with the Company's first year of Sarbanes-Oxley compliance.

Other Income (Expense), Net

	March 31,			
	2012	2011	\$ Change	% Change
Three months ended	\$ (44)	\$ 18	\$ (62)	(344)%

Other income (expense) represents non-operating revenue and expenses, earnings on cash and cash equivalents and interest expense related to long-term debt. The increase in other income (expense) for the three months ended March 31, 2012 as compared to the same period in 2011 was due primarily to interest expenses related to long-term debt of \$28,000.

Provision for Income Taxes

	March 31,			
	2012	2011	\$ Change	% Change
Three months ended	\$ 32	\$ 11	\$ 21	191%

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

Table of Contents**Liquidity and Capital Resources**

To date we have funded our operations primarily from the sale of our common stock, borrowings and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At March 31, 2012, we had \$21.7 million of working capital, including \$23.8 million in cash and cash equivalents.

Cash Flows

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

	March 31,	
	2012	2011
Three months ended:		
Cash used in operating activities	\$ (5,496)	\$ (3,090)
Cash provided by (used in) investing activities	4,244	(185)
Cash provided by (used in) financing activities	(267)	2,000
Net decrease in cash and cash equivalents	\$ (1,519)	\$ (1,275)

Cash flows used in operating activities

Net cash used in operating activities increased \$2.4 million to \$5.5 million for the three months ended March 31, 2012 compared to \$3.1 million for the three months ended March 31, 2011. The increased use of cash during the first quarter of 2012 was due primarily to increased inventory purchases to support higher sales levels in 2012.

Cash flows provided by (used in) investing activities

Net cash provided by investing activities was \$4.2 million for the three months ended March 31, 2012, compared to net cash used in investing activities of \$0.2 million for the three months ended March 31, 2011. During the first quarter of 2012, a short-term investment of \$5.0 million matured and was converted to cash, which was offset by uses of cash for payments for intellectual property and plant, property and equipment. During the first quarter of 2011, cash was used primarily for purchases of instruments to be placed at customer sites.

Cash flows provided by (used in) financing activities

Net cash used in financing activities was \$0.3 million for the three months ended March 31, 2012, compared to cash provided by financing activities of \$2.0 million for the three months ended March 31, 2011. During the first quarter of 2011, we drew down a \$2.0 million term loan on our credit facility. In the first quarter of 2012, we did not draw down any loans and repaid a portion of the long-term debt outstanding.

Table of Contents

In March 2010, we entered into a loan and security agreement with Square 1 Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to \$2 million and an equipment term loan in the amount of up to \$2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank's prime rate (3.25% as of March 31, 2012) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank's prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank's prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank's prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to \$3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

In March 2011, an additional loan was made available under the amended loan and security agreement for up to \$1.0 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank's prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank's prime rate plus 4.25%, or (b) 7.50%. This term loan matures in March 2014.

As of March 31, 2012, we had no outstanding loans on the line of credit or the 2011 equipment loan and had a balance of \$1.3 million used to finance 2010 equipment purchases and tenant improvements to our Carlsbad facility on the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% were due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that were then outstanding are payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

Pursuant to the terms of the loan and security agreement, we are required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior to the change of control event, incurring other indebtedness or liens with respect to our property, making distributions to our stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount we can borrow under the term loan to license genetic biomarkers to \$500,000. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights. We are currently in compliance with all ratios and covenants.

We have prepared cash flow forecasts which indicate, based on our current cash resources available, the availability of unutilized credit facilities, and our ability to access the equity markets, 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, expand our research and development, commercialization and manufacturing activities. 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 revenue growth;

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

the level of research and development investment required to maintain and improve our technology;

our need to acquire or license complementary technologies or acquire complementary businesses;

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

competing technological and market developments; and

changes in regulatory policies or laws that affect our operations.

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

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 accounting principles generally accepted in the United States (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, 2011 and there have been no material changes during the three months ended March 31, 2012.

Table of Contents

Contractual Obligations

Real property leases:

On February 8, 2010, we entered into a 91 month lease for a new 31,098 square foot facility in Carlsbad, California. The facility is part of a three-building office and research and development project located at 5964 La Place Court, Carlsbad, California, and the project totals 158,733 rentable square feet. Monthly rental payments of \$45,092 commenced on July 14, 2010 and increase 3% annually thereafter. We also pay our pro-rata share of the building and project maintenance, property tax, management and other costs subject to certain limitations. We have paid a \$55,000 security deposit and provided a \$500,000 standby letter of credit as security for the future rent as well as for up to \$2.0 million in landlord funded tenant improvements. The lease also provides for rights of first refusal for expansion within our building, subject to certain limitations.

In January 2012, we entered into a lease amendment for the adjoining facility space totaling an additional 22,000 square feet. We intend to utilize the additional space for storage initially, and build out for additional office and warehouse space in 2013. The lease amendment required an additional security deposit of \$22,000 to \$77,000 upon signing the amendment, and increases in our standby letter of credit to \$858,000 and security deposit to \$104,000 to be made upon the earlier of thirty days after the landlord's approval or deemed approval of the tenant improvement construction drawings or January 1, 2013. Also, the lease amendment requires additional rental payments of \$16,000 per month until the earlier of July 1, 2013 or we commence operations in the adjoining space, at which time the rent increases approximately \$35,000 per month, with annual increases of 3% to 4%. The lease amendment might require us to pay landlord a liquidated damage of \$258,524 in the event of a default by us that results in the early termination of the lease prior to a certain date. The term of the lease is also extended to 91 months after the earlier of July 1, 2013 or we commence operations in the adjoining space and our proportional share of common area maintenance, property management and taxes are increased under the provisions of the amendment to the lease.

The foregoing description of the lease amendment is qualified in its entirety by reference to the actual text of the agreement, a copy of which was filed with our Annual Report on Form 10-K for the year ended December 31, 2011.

Intellectual property:

Effective March 27, 2012, we entered into a Non-Exclusive License Agreement with Caliper Life Sciences, Inc. (the "License Agreement") which grants us a non-exclusive license under Caliper's microfluidics patent portfolio. In consideration for the license, we agreed to pay certain up-front and sales-based milestone payments, as well as a royalty on the sale of certain products. In addition, we obtained an unconditional release from any and all claims based upon any alleged infringement of the licensed patents prior to the effective date of the License Agreement.

Effective March 30, 2012, we entered into a Heads of Agreement with Advanced Liquid Logic, Inc. ("ALL") setting forth certain key terms to be contained in one or more definitive agreements to be negotiated and executed and pursuant to which we will be granted certain exclusive and non-exclusive licenses to use ALL's proprietary electro-wetting technology in conjunction with electrochemical detection in the development and commercialization of in-vitro diagnostics. Following execution of the definitive agreements, we have agreed to pay up to \$3,000,000 in license fees, contingent milestone payments, and an equity investment in ALL.

The foregoing descriptions of the License Agreement and the agreement with Advanced Liquid Logic are qualified in their entirety by reference to the actual text of the respective agreements, copies of which are filed with this Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

Off-Balance Sheet Arrangements

We have no other off-balance sheet arrangements except as follows:

We have unutilized credit facilities with Square 1 Bank that provides a revolving line of credit up to \$2.0 million and an unutilized equipment term loan totaling \$1.0 million at March 31, 2012.

We have provided a \$500,000 standby letter of credit as security for future rent to our landlord in conjunction with the lease of our Carlsbad facility.

ITEM 3. 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, in the future we may maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Interest Rate Risk

We have exposure to interest rate risk related to our variable rate borrowings. In 2010, we entered into a credit facility consisting of a revolving line of credit in the amount of \$2.0 million and an equipment term loan in the amount of up to \$2.0 million. In 2011, we amended the credit facility to provide an additional \$1.0 million of borrowings to finance equipment purchases. As of March 31, 2012, we had no outstanding loans on the line of credit or the 2011 equipment loan increase and had drawn \$2.0 million against the original 2010 equipment term loan. This loan bears an interest rate of 6.5%. As of March 31, 2012, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase 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 licensing agreement for intellectual property that requires payment in Euros. We currently have no material operations outside of the United States which diminishes the extent of any foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (Exchange Act), is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our internal control over financial reporting are the controls, processes and procedures designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2012. Based on that evaluation, we have concluded that our disclosure controls and procedures were not effective, at the reasonable assurance level, because of the identification of a material weakness in our internal control over financial reporting. A deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During the preparation of our December 31, 2011 financial statements, there were a number of errors identified by the external auditors and us, as well as other control deficiencies. These errors and deficiencies resulted in the need to record adjustments that were immaterial individually and in the aggregate; however, due to the combination of deficiencies, we determined that there was a reasonable possibility that a material misstatement to the annual or interim financial statements might not have been prevented or detected in a timely manner. Specifically, the level of monitoring of our financial closing and reporting process was insufficient to reduce the likelihood of detecting material adjustments to the Company's books and records. As a result, we identified a material weakness in the Company's internal control over financial reporting related to the supervision and review of our financial closing and reporting process as of December 31, 2011.

Table of Contents

Remediation of Material Weakness

We have devoted significant resources to addressing the material weakness in internal control over financial reporting and are committed to complete the overall remediation plan as expeditiously as possible. In order to improve our internal control over financial reporting and to remediate the identified material weakness, we have implemented the following:

Evaluated the staffing level and qualifications of finance department personnel, and made changes as deemed appropriate;

Evaluated the utilization of external resources, to provide greater assurance that these resources are effectively managed, and deployed, and made changes as appropriate; and

Formalized and enhanced policies and procedures governing financial reporting processes and related internal control and quality assurance, including documentation, checklists, audit trails and other evidence to support the financial statement balances and related disclosures to facilitate management review of the financial information.

We believe that the actions described above will strengthen our internal control over financial reporting and will address the material weakness.

While we have implemented remediation measures to address the material weakness in our internal controls over financial reporting, we have not yet validated, as of March 31, 2012, the effectiveness of our remediation efforts; therefore we have concluded that disclosure controls and procedures are not effective as of March 31, 2012. No material weakness will be considered remediated until the remediation measures we have implemented have operated for an appropriate period, have been tested, and we have concluded that they are operating effectively.

We have reviewed our assessment of the material weakness and our remediation plans, and the status of its implementation and effectiveness with our audit committee. We will continue to assess the effectiveness of our remediation efforts in connection with our future evaluations of internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Except as otherwise discussed above, 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.

There were no other changes to our internal control over financial reporting during the period covered by this report that has 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 during the ordinary course of our business. We believe that there are currently no claims or legal actions that would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors during the three months ended March 31, 2012. For additional information on risk factors, refer to Part I, Item 1A. Risk Factors in our annual report on Form 10-K for the year ended December 31, 2011.

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

Unregistered Sales of Equity Securities

None.

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.

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 10, 2012

/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.

10.27**	Non-Exclusive License Agreement by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Caliper Life Sciences Inc. dated effective as of March 27, 2012.
10.28	Executive Employment Agreement, dated March 23, 2012, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Richard B. Slansky. (Incorporated by reference herein from Exhibit 10.1 to our Form 8-K filed with the Securities and Exchange Commission on April 12, 2012)
10.29**	Heads of Agreement by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Advanced Liquid Logic, Inc. dated effective as of March 30, 2012.
10.30	Separation Agreement and General Release by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Paul Ross, dated April 19, 2012.
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*	XBRL Instance Document
101*	XBRL Taxonomy Extension Schema Document
101*	XBRL Taxonomy Calculation Linkbase Document
101*	XBRL Taxonomy Label Linkbase Document
101*	XBRL Taxonomy 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.

** Confidential Treatment Request
Management Compensation Plan