GenMark Diagnostics, Inc.
Form 10-Q
November 08, 2012
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 September 30, 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)

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 November 2, 2012 was 32,665,444.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	As of September 30, 2012 (Unaudited)	As of December 31, 2011
Current assets		
Cash and cash equivalents	$ 53,371	$ 25,320
Short-term investments		5,000
Restricted cash	3,594	
Accounts receivable, net of allowance of $53 and $98 at September 30, 2012 and December 31, 2011, respectively	1,152	1,098
Inventories	2,131	2,168
Other current assets	183	322
Total current assets	60,431	33,908
Property and equipment, net	5,215	2,836
Intangible assets, net	1,868	1,362
Other long-term assets	1,128	80
Total assets	$ 68,642	$ 38,186
Current liabilities		
Accounts payable	$ 2,357	$ 1,201
Accrued compensation	2,136	1,521
Current portion of long-term debt	852	1,000
Other current liabilities	2,371	2,659
Total current liabilities	7,716	6,381
Long-term liabilities		
Long-term debt	67	583
Other non-current liabilities	743	588
Total liabilities	8,526	7,552
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued		
Common stock, $0.0001 par value; 100,000 authorized; 32,667 and 20,478 issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	3	2
Additional paid-in capital	246,422	199,531
Accumulated deficit	(185,873)	(168,463)
Accumulated other comprehensive loss	(436)	(436)
Total stockholders equity	60,116	30,634
Total liabilities and stockholders equity	$ 68,642	$ 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 September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Product revenue	$ 5,194	$ 1,206	$ 10,876	$ 2,765
License and other revenue	62	110	150	210
Total revenue	5,256	1,316	11,026	2,975
Cost of sales	3,027	1,785	6,878	4,580
Gross profit (loss)	2,229	(469)	4,148	(1,605)
Operating expenses				
Research and development	4,467	1,903	9,437	6,759
Sales and marketing	1,485	1,328	4,264	3,767
General and administrative	2,510	2,405	7,743	6,338
Total operating expenses	8,462	5,636	21,444	16,864
Loss from operations	(6,233)	(6,105)	(17,296)	(18,469)
Other (expense)				
Other expense, net	(2)	(180)	(15)	(50)
Interest (expense) income, net	(16)	(29)	(56)	6
Total other (expense), net	(18)	(209)	(71)	(44)
Loss before income taxes	(6,251)	(6,314)	(17,367)	(18,513)
(Provision) benefit for income taxes	(1)	1	(43)	(21)
Net loss	$ (6,252)	$ (6,313)	$ (17,410)	$ (18,534)
Net loss per share, basic and diluted	$ (0.20)	$ (0.31)	$ (0.71)	$ (1.20)
Weighted average number of shares outstanding	31,751	20,043	24,370	15,393
Condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2012 and 2011				
Net loss	$ (6,252)	$ (6,313)	$ (17,410)	$ (18,534)
Foreign currency translation adjustment		56		(8)
Comprehensive loss	$ (6,252)	$ (6,257)	$ (17,410)	$ (18,542)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (17,410)	$ (18,534)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	918	948
Share-based compensation	1,509	1639
Change in allowance for doubtful accounts	(45)	71
Non-cash inventory adjustments	563	428
Changes in operating assets and liabilities:		
Accounts receivable	(9)	(117)
Inventories	(402)	(1,448)
Other current assets	92	1,741
Accounts payable	907	510
Accrued compensation	871	22
Other current	523	731
Net cash used in operating activities	(12,483)	(14,009)
Investing activities:		
Restricted cash	(3,594)	
Purchases of preferred securities	(1,000)	
Payments for intellectual property licenses	(1,306)	(728)
Purchases of property and equipment	(2,919)	(1,172)
Maturities (purchases) of short-term investments	5,000	(5,000)
Net cash used in investing activities	(3,819)	(6,900)
Financing activities:		
Proceeds from issuance of common stock	48,300	34,532
Costs incurred in conjunction with public offering	(3,226)	(2,790)
Proceeds from borrowings	835	2,000
Proceeds from stock option exercises	52	
Principal repayment of long-term debt	(1,608)	(167)
Net cash provided by financing activities	44,353	33,575
Effect of foreign exchange rate changes		6
Net increase in cash and cash equivalents	28,051	12,672
Cash and cash equivalents at beginning of period	25,320	18,329
Cash and cash equivalents at end of period	$ 53,371	$ 31,001

Supplementary schedule of non-cash transactions:		
Property and equipment purchased with capital lease	$ 109	$
Transfer of systems from property and equipment into inventory	124	46
Property and equipment costs incurred but not paid included in accounts payable and other liabilities	249	163

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-interest, 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 (the US 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 condensed 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 $185.9 million at September 30, 2012. Cash and cash equivalents at September 30, 2012 were $53.4 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, the availability of unutilized credit facilities and the Company s ability to access the equity markets 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 of the financial statements for the interim period have been included. Operating results for the nine months ended September 30, 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 September 30, 2012, and for the three and nine months ended September 30, 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 for the fiscal year ended December 31, 2011 filed with the Securities and Exchange Commission (SEC) on March 21, 2012.

Segment Information

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 additional disclosures in the notes to the Company s condensed consolidated financial statements, and 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 classifies 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. Long-term investments are based on the initial acquisition price in the current quarter defined as unobservable inputs for which little or no market data exists. The Company classifies such items as Level 3.

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.

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and includes $3,594,000 at September 30, 2012 held as security for the Company s term loan, letter of credit, and line of credit with First PacTrust Bankcorp.

Long-Term Investments

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

Concentration of Risk

The Company had sales to one specialty diagnostic reference lab customer representing approximately 66% and 58% of total revenues for the three and nine months ended September 30, 2012, respectively. 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 Cost of sales in the accompanying condensed consolidated statements of operations and comprehensive loss. Shipping and handling costs were approximately $132,000 and $134,000 for the nine months ended September 30, 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

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.

Table of Contents

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, estimated useful life for laboratory equipment from three to five years and estimated useful life of office equipment from between two and four years to five years. These changes were based upon a review of the current and projected utilization of the respective assets, which indicated that our prior estimation of useful lives of these assets should be revised.

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.

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. On September 19, 2012, the Company placed Osmetech Ltd into liquidation. It is anticipated that the Reorganization will not trigger any material U.S. federal or U.K. income tax expense. 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. subsidiary, CMS.

2. Share-Based Compensation

The Company recognizes share-based compensation expense related to share options and restricted stock issued to employees, consultants, and directors in exchange for services. The compensation expense is based on the fair value of the awards, which are determined by utilizing various assumptions regarding the underlying attributes of the options and shares. The estimated fair value of options granted and restricted stock, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a modified 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 grantee 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.

Table of Contents

On June 3, 2010, the Company exchanged all of the outstanding options under the U.S. Plan for options under the 2010 Equity Incentive Plan (the 2010 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 closing price of the Company s shares as quoted on the NASDAQ stock market on the date of grant. Options granted prior to June 3, 2010 under the U.S. Plan were exercisable at a price equal to the closing price of the Osmetech plc s shares as quoted 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 one and four 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 September 30, 2012, there were 131,404 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 nine months ended September 30, 2012. There were warrants to purchase 88,317 shares of the Company s common stock that expired on June 30, 2012. There were no new warrants issued during the nine months ended September 30, 2012.

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2011	1,598,894	$ 5.38
Granted	313,866	$ 4.55
Exercised	(28,416)	$ 4.54
Cancelled	(382,830)	$ 5.38
Outstanding at September 30, 2012	1,501,514	$ 5.23
Exercisable at September 30, 2012	766,984	$ 5.67

As of September 30, 2012, there were 1,364,194 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.20 years, and an aggregate intrinsic value of $5,378,692.

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 nine months ended September 30, 2012 with the following assumptions:

Expected volatility (%)	75.00
Expected life (years)	5.91
Risk free rate (%)	0.98
Expected dividend yield (%)	0.00

The Company s non-vested restricted share award (RSA) activity for the nine months ended September 30, 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	823,334	$ 4.25
Vested	(110,570)	$ 4.25
Cancelled or expired	(147,792)	$ 4.24

Non-vested at September 30, 2012	968,034	$ 4.23

As of September 30, 2012, there was $2.8 million of unrecognized compensation cost related to RSAs. That cost is expected to be recognized over a weighted average-period of 3.05 years. The total fair value of restricted shares vested during the nine months ended September 30, 2012 and 2011 was $0.5 million and $1.2 million, respectively.

Table of Contents

RSAs may be granted at the discretion of the Board of Directors under the 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 nine months ended September 30, 2012, the Company awarded 823,334 shares of restricted stock, which had a fair value at the date of grant ranging from $4.14 to $5.60 per share. During the nine months ended September 30, 2011, the Company awarded 435,169 shares of restricted stock, which had a fair value at the date of grant ranging from $3.95 to $5.85 per share. Compensation under these restricted stock awards is charged to expense over the restriction period and amounted to $754,204 and $646,000 for the nine months ended September 30, 2012 and 2011, respectively.

There were no stock compensation costs capitalized into assets as of September 30, 2012.

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):

	September 30,	
	2012	2011
Common stock options outstanding	1,502	1,554
Warrants		88
Restricted Stock unvested, issued and held in escrow	968	427
Total	2,470	2,069

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 continued 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 and (ii) June 30, 2012. The warrants expired unexercised at June 30, 2012.

4. Inventory

Inventory on hand as of September 30, 2012 and December 31, 2011 was comprised of the following (in thousands):

	September 30, 2012	December 31, 2011
Raw materials	$ 443	$ 1,012
Work-in-process	883	706
Finished goods	805	450
	$ 2,131	$ 2,168

8

Table of Contents

5. Property and Equipment, net

Property and equipment was comprised of the following as of September 30, 2012 and December 31, 2011 (in thousands):

	September 30, 2012	December 31, 2011
Property and equipment at cost:		
Machinery and laboratory equipment	$ 2,819	$ 2,539
Instruments	5,719	3,918
Office equipment	989	848
Leasehold improvements	1,311	583
Total property and equipment at cost	10,838	7,888
Less accumulated depreciation	(5,623)	(5,052)
Property and equipment, net	$ 5,215	$ 2,836

Depreciation expense was $774,000 and $869,000 for the nine months ended September 30, 2012 and 2011, respectively.

6. Intangible assets

Intangible assets as of September 30, 2012 and December 31, 2011, respectively, comprise the following (in thousands):

	September 30, 2012			December 31, 2011		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Licensed intellectual property	$ 3,124	$ (1,256)	$ 1,868	$ 2,474	$ (1,112)	$ 1,362

During the three and nine months ended September 30, 2012, the Company acquired exclusive and non-exclusive licenses for various microfluidic technologies for a license fee of $250,000 and $400,000, respectively which will be amortized over a 10 year period of expected use.

Licenses have a weighted average remaining amortization period of 8.5 years as of September 30, 2012. Amortization expense for intangible assets amounted to $144,000 and $78,000 for the nine months ended September 30, 2012 and 2011, respectively. Estimated future amortization expense for these licenses (assuming no impairment charges) is as follows (in thousands):

Years Ending September 30,	
2013	$ 216
2014	216
2015	216
2016	213
2017	209
Thereafter	798
Total	$ 1,868

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 $2.0 million and an equipment term loan in the amount of up to $2.0 million. Based upon certain

financial covenants, interest on the revolving line of credit was either (i) the greater of (a) the bank s prime rate (3.25% as of September 30, 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 matured in July 2011 and the term loan would have matured in July 2013 (but was repaid in September 2012 see below). 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. The loan and security agreement was further amended in July 2012 to extend the period of availability of funds for the revolving line of credit and second equipment term loan to September 12, 2012.

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 was 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 would have matured in March 2014.

Pursuant to the terms of the Square 1 loan and security agreement, the Company was required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the Square 1 loan and security agreement included several restrictive covenants, including requirements that the Company obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt was 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 limited the amount the Company could have borrowed 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 will all ratios and covenants.

As of September 19, 2012, the Company replaced the Square 1 loan and security agreement with the following three loans from First PacTrust Bankcorp, initially secured with cash and reported as restricted cash of $3,594,000.

1) The Company increased the letter of credit to $758,000 with First PacTrust Bankcorp from the previous Square 1 Bank letter of credit of $500,000. The increase in the letter of credit was required pursuant to our second and third amendments to lease for the expansion space with the landlord.

2) The Company created a variable rate term loan with First PacTrust Bankcorp in the amount of $836,000 with an initial interest rate of 3.75% and expiring July 2013. This term loan replaced the Square 1 equipment loan of the same amount with an interest rate of 6.75% and expiring July 2013.

3) The Company established a revolving line of credit with First PacTrust Bankcorp in the amount of $2.0 million to be used for equipment purchases, with an initial interest rate of 3.75% and expiring September 2013. This line of credit replaced the Square 1 line of credit. There was no outstanding balance with this revolving line of credit as of September 30, 2012.

Pursuant to the terms of the First PacTrust Bankcorp business loan agreements, 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, as specified under the Square 1 loan and security agreement.

8. Lease payable

In January 2012, the Company entered into a capital 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.

Future minimum lease payments required over the next five years are as follows (in thousands):

Years Ending September 30,	Amount
2013	$ 25
2014	25
2015	24
2016	24
2017	6

Total future minimum payments	104
Less amounts representing interest	(20)
Net carrying value of lease payable	84
Less current portion	(17)
Non-current portion	$ 67

Table of Contents

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 September 30, 2012 and December 31, 2011 (in thousands):

	September 30, 2012			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents	$ 23	$	$	$ 23
Long-term investment	$	$	$ 1,000	$ 1,000

	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

The Company has not elected the fair value measurement option for any of its other financial assets or liabilities. The Company has estimated the fair value of its financial liabilities by using either (1) a discounted cash flow analysis using an appropriate market discount rate for similar types of instruments, or (2) a present value model and an interest rate that includes a credit value adjustment based on the estimated value of the property that serves as collateral for the underlying debt. The Level 3 carrying value of the Company s long-term investments is based on the initial acquisition price in the current quarter. The fair values of certain additional financial liabilities at September 30, 2012 and December 31, 2011 (fair value measurements categorized as Level 2 of the fair value hierarchy) are as follows (in thousands):

	September 30, 2012	December 31, 2011

	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Financial liabilities:				
Long-term debt	$ 919	$ 901	$ 1,583	$ 1,501

The fair value of long-term debt at September 30, 2012 and December 31, 2011 was $901,000 and $1,501,000, respectively, based on current interest rates for comparable loans. The method for computing fair value was determined using a net present value model. Long-term debt includes current portions of long-term debt and capital lease obligations of $852,000 and $1,000,000 as of September 30, 2012 and December 31, 2011, respectively.

Table of Contents

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 September 30, 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 $43,000 and $22,000 for the nine months ended September 30, 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 September 30, 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 $143,000 as of September 30, 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 September 30, 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 September 30,2012, the Company is no longer subject to U.S. federal, state, local examinations for years before 2006.

11. Common stock offering

On June 26, 2012, the Company completed a public offering of 11,500,000 shares of common stock at a price of $4.20 per share, including 1,500,000 shares of common stock purchased by the underwriter pursuant to an over-allotment option, which the underwriters exercised in full. The Company raised approximately $45.1 million in net proceeds after deducting underwriting discounts and commissions of $2.9 million and other offering expenses of $0.3 million.

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 and nine months ended September 30, 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, new product launches, 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 te 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 or implied by 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 Item 1A of Part II of this Quarterly Report. We assume no responsibility 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 September 30, 2012, we had an installed base of 255 analyzers, or placements, with our customers.

We have developed seven tests for use with our XT-8 system and expect to 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 is intended to simultaneously detect and differentiate 14 clinically relevant viruses from patients with influenza-like illnesses. Our Respiratory Viral Panel test received a 510(k) clearance from the FDA in September 2012. Our eSensor technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test, our Thrombophilia Risk Test and now our Respiratory Viral Panel Test. We also have developed a Hepatitis C Virus genotyping assay, a 3A4/3A5 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.

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.

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 nine months ended September 30, 2012 and 2011 were approximately $17.4 million and $18.5 million, respectively. As of September 30, 2012, we had an accumulated deficit of $185.9 million. Our operations to date have

Table of Contents

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.

Market opportunity

We believe the global market for molecular diagnostics to be approximately $4.5 billion and growing at a rate of approximately 15% per year over the course of the next several years based on research published by leading market research firms. Although we believe the global market for molecular diagnostics is approximately $4.5 billion, our existing technology is suited to address a subset of this market that approximates $0.9 billion in 2012. Our XT-8 instrument and related reagents are currently only sold in the U.S. market.

We anticipate that our NexGen system currently under development would, when completed, expand the market opportunity for our technology so that we could address up to half of the total global market for molecular diagnostics. We anticipate that the market for the molecular diagnostic tests on which our NexGen system will focus to increase by more than 20% per year over the next several years. Many factors are driving growth of this market, including the expansion of genetic testing for disease predisposition, advances in personalized medicine, such as the tailoring of therapies to those individuals most likely to respond, and increased demand for infectious disease diagnostics panels. The markets for pharmacogenetic testing, cancer diagnostics and infectious disease diagnostic panels are anticipated to grow at 30%, 17% and 14% per annum, respectively, over the next several years.

Growth in installed based and available market

The aggregate installed base of our eSensor system has grown from 37 at the end of 2009 to 82 at the end of 2010 to 167 at the end of 2011. As of September 30, 2012, we had an installed base of 255 eSensor systems. We currently expect our aggregate installed base of eSensor systems to grow to in excess of 267 systems by the end of 2012.

We believe that our NexGen system, when completed, will expand the number of domestic labs that we can target as customers from the approximately 1,000 U.S. labs that have the capability to run our existing XT-8 system today to the more than 5,000 U.S. labs that currently perform diagnostic testing. While our initial test menu focus with our NexGen system will be in the area of infections diseases, we anticipate that our NexGen system will allow us to develop tests that address a critical clinical need but are not currently available on our XT-8 system. Although our NexGen system will expand our addressable markets, we anticipate that our XT-8 system will continue to be used to perform existing tests for inherited diseases and pharmacogenetics, amongst others, until such time as we develop those tests for our NexGen system. As a result, we expect that customers will continue to use our existing XT-8 system after the introduction of our NexGen system for the foreseeable future.

Results of Operations Three months ended September 30, 2012 compared to the three months ended September 30, 2011 *(in thousands)*

Revenue

	September 30,			
	2012	**2011**	**$ Change**	**% Change**
Three months ended	$ 5,256	$ 1,316	$ 3,940	299%

Our product revenue consists primarily of revenue from the sale of reagents (consumables) with a small component due to our sale of instruments and other revenue. Our revenue for the quarter ended September 30, 2012 increased by $3,950,000, or 299% compared to the same quarter of 2011 due to higher reagent revenues of $5.1 million versus $1.1 million in the comparable period ended September 30, 2011. This increase in reagent revenue was primarily driven by a 57 % increase in the number of our installed base of analyzers to 255 at September 30, 2012 from 141 as of September 30, 2011, 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 about $39,000 per analyzer per year at September 30, 2011 to about $93,000 per analyzer per year at September 30, 2012. The increase was not attributable to any one assay; however, our IVD (In Vitro Diagnostics) assay revenue in pharmacogenetics and infectious disease increased significantly more than our other assay panels.

Cost of Sales and Gross Profit (Loss)

	September 30,			
	2012	2011	$ Change	% Change
Cost of sales-three months ended	$ 3,027	$ 1,785	$ 1,242	70%
Gross profit (loss)-three months ended	$ 2,229	$ (469)	$ 2,698	575%

The increase in cost of sales for the quarter ended September 30, 2012 compared to the quarter ended September 30, 2011, was directly related to the increase in reagent (consumable) sales and instrument placements. We incurred higher manufacturing salaries expense of $150,000 to support the increase in production volumes, and incurred higher depreciation and warranty expenses of $168,000, related to the increased reagent sales and number of instrument placements in 2012. The improvement in gross profit of $2,698,000 was primarily due to the increase in reagent (consumable) sales and instrument placements. Additionally, the increase in volume allowed for increased absorption of our fixed manufacturing costs. Further, we have continued to realize improved manufacturing efficiencies due to sales volume increases.

Table of Contents

Operating Expenses

Research and Development

	September 30,			
	2012	2011	$ Change	% Change
Three months ended	$ 4,467	$ 1,903	$ 2,564	135%

For the quarter ended September 30, 2012, research and development expenses increased 135% compared to the quarter ended September 30, 2011. The increase was primarily driven by $1,914,000 associated with development of our NexGen platform. The creation of two new departments, Software Development and Product Technical Support to improve our product reliability and enhance our product effectiveness, resulted in increases of $305,000 and $180,000 respectively. The increases in NexGen, Product Technical Support, and Software were partially offset by clinical trial cost savings of $188,000 as we concluded our clinical trials in 2011.

Sales and Marketing

	September 30,			
	2012	2011	$ Change	% Change
Three months ended	$ 1,485	$ 1,328	$ 157	12%

The increase in sales and marketing expense for the quarter ended September 30, 2012, compared to the quarter ended September 30, 2011, was driven by increased salaries expense of $275,000 associated with our commitment to invest in our commercial organization and increased headcount to facilitate sales growth. Commission expenses increased $30,000 and trade show expenses increased $26,000. These increases were offset by a decrease of $22,000 in marketing communications and a $28,000 decrease in recruiting expense.

General and Administrative

	September 30,			
	2012	2011	$ Change	% Change
Three months ended	$ 2,510	$ 2,405	$ 105	4%

General and administrative expense was $2,510,000 for the quarter ended September 30, 2012, an increase of $105,000, or 4%, compared to the quarter ended September 30, 2011. The increase was primarily due to facility expense of $148,000.

Other (Expense), Net

	September 30,			
	2012	2011	$ Change	% Change
Three months ended	$ (18)	$ (209)	$ (191)	(91)%

Other income (expense) represents non-operating revenue and expenses, earnings on cash and cash equivalents and interest expense related to long-term debt. The change in other income (expense) for the quarter ended September 30, 2012, compared to the quarter ended September 30, 2011, was $191,000, due primarily to a $165,000 recovery of a previously reserved note.

(Provision) Benefit for Income Taxes

	September 30,			
	2012	2011	$ Change	% Change
Three months ended	$ (1)	$ 1	$ (2)	(200)%

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

Results of Operations Nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 *(in thousands)*

Revenue

	September 30,			
	2012	2011	$ Change	% Change
Nine months ended	$ 11,026	$ 2,975	$ 8,051	271%

The increase in revenue for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was due to higher reagent (consumables) revenues of $10.4 million in 2012 versus $2.6 million in the comparable period in 2011. This increase in reagent revenue was primarily driven by a 57 % increase in the number of our installed base of analyzers to 255 at September 30, 2012 from 141 as of September 30, 2011,

Table of Contents

along with an increase in consumable utilization per analyzer. Pricing changes were not material cause of our significant increase in revenue. Our average annuity per analyzer increased from about $39,000 per analyzer per year at September 30, 2011 to about $93,000 per analyzer per year at September 30, 2012. The increase was not attributable to any one assay; however, our IVD assay revenue in pharmacogenetics and infectious disease increased significantly more than our other assay panels . In addition to the increase in reagent (consumables) revenue, higher instrument sales during the nine months ended September 30, 2012 resulted in an additional $238,000 of revenue for the period over the same period in 2011.

Cost of Sales and Gross Profit (Loss)

	September 30,			
	2012	2011	$ Change	% Change
Cost of sales-nine months ended	$ 6,878	$ 4,580	$ 2,298	50%
Gross profit (loss)-nine months ended	$ 4,148	$ (1,605)	$ 5,753	358%

The increase in cost of sales for the nine months ended September 30, 2012 compared to the nine months ended September 30, 2011 was directly related to the increase in reagent (consumable) sales. Increased direct and indirect labor of $622,000 was required to support increased production and sales volumes. An increase in warranty expense of $246,000 and an increase of $110,000 in depreciation expense were related to the larger number of instrument placements in 2012. The improvement to gross profit of $5,753,000 was primarily due to two factors: volume and manufacturing efficiencies. First, the increase in volume allowed us to increase absorption of our fixed manufacturing costs. And second, we have continued to realize improved manufacturing efficiencies since relocating manufacturing operations from Pasadena, CA to Carlsbad, CA, which has resulted in substantially improved manufacturing yields.

Operating Expenses

Research and Development

	September 30,			
	2012	2011	$ Change	% Change
Nine months ended	$ 9,437	$ 6,759	$ 2,678	40%

The increase in research and development expense of $2,678,000 for the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011, was primarily due to $2,828,000 associated with development of our NexGen platform. The creation of new departments to improve our product reliability and enhance our product effectiveness resulted in an increase of $614,000 in Software Development, $377,000 in Product Technical Support, and $167,000 in Customer Technical Support, in addition to increased Legal expense of $263,000 due to the hiring of an in-house counsel. These increases were offset by lower Assay Development expense of $1,244,000 in 2012 since there were no clinical trials ongoing this year.

Sales and Marketing

	September 30,			
	2012	2011	$ Change	% Change
Nine months ended	$ 4,264	$ 3,767	$ 497	13%

The increase of $497,000 in sales and marketing expense for the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011 was driven by increased salaries of $570,000 associated with our commitment to invest in our commercial organization and increased headcount to facilitate growth, along with an increase in commissions of $90,000. The increases were offset by a decrease in facility allocation expense of $191,000.

General and Administrative

	September 30,			
	2012	2011	$ Change	% Change
Nine months ended	$ 7,743	$ 6,338	$ 1,405	22%

General and administrative expense was $7,743,000 for the nine months ended September 30, 2012 compared to $6,338,000 for the same period last year. The increase of $1,405,000 was due primarily to increased administrative salaries of $662,000, increased expenses associated with audit fees of $183,000 and Sarbanes Oxley 404 compliance measures of $194,000 and outside services of $184,000, which were partially offset by lower legal fees of $107,000.

Other (Expense), Net

	September 30,			
	2012	2011	$ Change	% Change
Nine months ended	$ (71)	$ (44)	$ (27)	(61)%

Other income (expense) represents non-operating revenue and expenses, earnings on cash and cash equivalents and interest expense related to long-term debt. The change in other income (expense) for the nine months ended September 30, 2012, compared to the nine months ended September 30, 2011, was due primarily to interest expense.

Table of Contents

(Provision) Benefit for Income Taxes

	September 30, 2012	2011	$ Change	% Change
Nine months ended	$ (43)	$ (21)	$ 22	105%

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

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 September 30, 2012, we had $52.7 million of working capital, including $53.4 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)*:

	September 30, 2012	2011
Nine months ended:		
Cash used in operating activities	$ (12,483)	$ (14,009)
Cash (used in) investing activities	(3,819)	(6,900)
Cash provided by financing activities	44,353	33,575
Effect of foreign exchange rate changes		6
Net increase in cash and cash equivalents	$ 28,051	$ 12,672

Cash flows used in operating activities

Net cash used in operating activities decreased $1.5 million to $12.5 million for the nine months ended September 30, 2012 compared to $14.0 million for the nine months ended September 30, 2011. The decrease in cash used in operating activities was primarily due to our lower net loss of $1.1 million for the nine months ending September 30, 2012 compared to the prior year period. This amount is adjusted by an increase in accounts payable of $0.4 million, accrued compensation of $0.9 million in operating assets and liabilities, a decrease in inventory of $1.0 million, a decrease in other current assets of $1.6 million due to Therapeutic tax credit received in the first quarter of 2011 and a decrease in share-based compensation of $0.1 million.

Cash flows used in investing activities

Net cash used in investing activities was $3.8 million for the nine months ended September 30, 2012, compared to net cash used in investing activities of $6.9 million for the nine months ended September 30, 2011. During the first quarter of 2012, a short-term investment of $5.0 million matured and was converted to cash. This was offset by an increased use of cash for payments of intellectual property of $1.3 million and plant, property and equipment of $2.9 million, which was mainly for purchases of instruments to be placed at customer sites and partly for tenant improvements of our existing and expanding facility. We used 3.6 million in restricted cash and $1 million in purchasing preferred securities.

Cash flows provided by financing activities

Net cash provided by financing activities was $44.4 million for the nine months ended September 30, 2012, compared to cash provided by financing activities of $33.6 million for the nine months ended September 30, 2011. During the second quarter of 2012, we issued common stock netting $45.1 million after offering costs. During the second quarter of 2011, we issued common stock netting $31.7 million after offering costs. During the first quarter of 2011, we also drew down a $2.0 million term loan on our credit facility. In 2012, we have not drawn down any loans and have repaid a substantial portion of the debt outstanding, e.g., the entire remaining balance is recorded as current portion of long-term debt.

17

Table of Contents

In June 2012, we completed a public offering of 11.5 million shares of common stock at a price of $4.20 per share, including 1.5 million shares of common stock purchased by the underwriters pursuant to an over-allotment option, which generated approximately $45.1 million in net proceeds after deducting underwriting discounts and commissions of $2.9 million and other offering expenses of $0.3 million, which we intend to use for research and development as it relates to acceleration of menu expansion and development of our NexGen System, as well as expansion of our U.S and global commercial organizations.

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, 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 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 and improve our NexGen 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.

Table of Contents

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 nine months ended September 30, 2012.

Contractual Obligations

Real property leases:

On February 8, 2010, we entered into a 91 month lease for a new 31,098 square foot facility at 5964 La Place Court in Carlsbad, California. The facility is part of a three-building office and research and development project located at 5962, 5964 and 5966 La Place Court, Carlsbad, California, and the project totals 158,733 rentable square feet. Our 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 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. We exercised a right to expand our premises and accelerate the expansion premises commencement date. As part of our expansion, we are required to increase the amount of our standby letter of credit from $500,000 to $758,000 and increase our security deposit from $55,000 to $77,000.

In January 2012, we entered into a second lease amendment for the adjoining facility space totaling an additional 22,000 square feet. We intended to utilize the additional space for storage initially, and we are now building the expansion space to provide for additional manufacturing, office and warehouse space in 2013 and beyond.

In August 2012, we entered into a third lease amendment requiring an additional security deposit of $22,000 and an additional $258,000 in our standby letter of credit 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. As of September 30, 2012, both the additional security deposit and the standby letter of credit were provided to our landlord and recorded as other long term assets and restricted cash, respectively. Also, the lease amendment requires additional rental payments of $34,000 per month, commencing January 1, 2013 or the day immediately preceding the expanded premises commencement date, at which time the rent increases to approximately $82,000 per month, with annual increases of 3% to 4%. The term of the lease is also extended to June 30, 2021.

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, with the Third Amendment to Lease attached hereto.

Intellectual property:

Effective July 26, 2012, we, through our subsidiary Clinical Micro Sensors, Inc., entered into a Development Collaboration and License Agreement with Advanced Liquid Logic, Inc. (ALL). Under the terms of the Agreement, we established with ALL a collaborative program to develop in-vitro diagnostic products incorporating ALL s proprietary electro-wetting technology in conjunction with our electrochemical

detection. We paid ALL an upfront license payment of $250,000, purchased approximately $1,000,000 in ALL preferred stock, and agreed to pay up to $1,750,000 in potential additional milestone payments. The milestone payments are contingent upon reaching certain development, approval and commercial launch events with a product incorporating ALL s proprietary electro-wetting technology. In addition, subject to meeting certain conditions, ALL will be the exclusive supplier of certain product components that incorporate ALL s proprietary electro-wetting technology. The foregoing description of the Development Collaboration and License Agreement with ALL is qualified in its entirety by reference to the actual text of the agreement, a copy of which we are filing with this Quarterly Report on Form 10-Q for the quarter ending September 30, 2012, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Table of Contents

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.The foregoing description of the Non-Exclusive License Agreement with Caliper Life Sciences Inc., is qualified in its entirety by reference to the actual text of the respective agreement, a copy of which is filed with the Quarterly Report on Form 10-Q for the quarter ended March 31, 2012.

Manufacturing and supply:

Effective August 3, 2012, we, through our subsidiary Clinical Micro Sensors, Inc., entered into a three-year XT-8 Instrument Supply Agreement with Leica Biosystems Melbourne Pty Ltd (Leica). Under the terms of the agreement, we commit to order instruments and spare parts exclusively from Leica, provided that Leica complies with certain product specifications, including but not limited to, design, functional, technical, scientific and packaging, as well as certain delivery and purchase order requirements. We agreed to provide Leica updated 12-month rolling, non-binding forecasts prior to the 15th day of each month. We agreed to place purchase orders at least three (3) months in advance of the specified delivery date. Prices for instruments and spare parts were negotiated between the parties and are considered proprietary to us and Leica. We are able to terminate the agreement with six (6) months prior written notice.

Leica provides us with a manufacturing warranty, whereby Leica warrants, among other things, that the products will be free from material defects and will conform to specifications for a designated period of time after delivery. Our remedies under the terms of the agreement include repair by Leica of the defective product or replacement of any such product. In addition, Leica has agreed to indemnify us from all liabilities arising from, or related to, a third party claim arising from (i) the gross negligence or willful misconduct of Leica, (ii) the breach or violation by Leica of any applicable law or regulation, (iii) any modifications to the products or our specifications or manufacturing instructions made by Leica not authorized by us and (iv) the improper use of the products by Leica.

The foregoing description of the XT-8 Instrument Supply Agreement with Leica is qualified in its entirety by reference to the actual text of the agreement, a copy of which we are filing with this Quarterly Report on Form 10-Q for the quarter ending September 30, 2012, with portions omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

Off-Balance Sheet Arrangements

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

We terminated our unutilized credit facilities with Square 1 Bank that provided for a revolving line of credit up to $3.0 million and created unutilized credit facilities with First PacTrust Bankcorp (PacTrust) that provided for a revolving line of credit up to $2.0 million. We also exchanged an equipment term loan with Square 1 Bank with a remaining balance of $836,000 at 6.75% interest with a term loan with PacTrust for the same amount at 3.75% interest at September 19, 2012.

We terminated a $500,000 standby letter of credit with Square 1 Bank and provided a $758,000 standby letter of credit with PacTrust as security for future rent to our landlord in conjunction with the lease of our Carlsbad, California 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 September 2012, 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 $0.8 million, both of which carry an interest rate of 3.75%. As of September 30, 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.

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. 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 designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the Exchange Act) is recorded, processed, summarized and reported within the

Table of Contents

specified time periods and 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 management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012 as required by paragraph (b) of Rule 13a-15 or Rule 15d-15 of the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of that date, our disclosure controls and procedures as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act were not effective at the reasonable assurance level because of the identification of a material weakness in our internal control over financial reporting, described below, which we view as an integral part of our disclosure controls and procedures.

During the preparation of our 2011 financial statements, there were current period and prior period errors identified by our external auditors and our management, as well as other control deficiencies. These errors and deficiencies resulted in the need to record adjustments that were immaterial individually and in the aggregate; however, due to the quantity of deficiencies, our management 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 our books and records. As a result, our management identified a material weakness in our internal control over financial reporting related to the supervision and review of our financial closing and reporting process as of December 31, 2011.

Remediation of Material Weakness

Our management is currently addressing the material weakness in internal control over financial reporting and is committed to remediating it as expeditiously as possible. Our management has devoted significant time and resources to the remediation effort. Our management has taken the following steps to improve our internal control over financial reporting and to remediate the identified material weakness:

- Evaluated the finance department management and the staff qualifications and made changes including the replacement of the chief financial officer, the controller and key accounting staff positions;
- Implemented new control procedures over the utilization of external resources including, but not limited to, our service provider for stock compensation management and payroll processing;
- Developed an implementation plan to deploy additional software systems to assist in automating and controlling certain financial processes that include payroll, procurement and fixed assets; and
- Implemented structured and formalized internal control procedures that include the use of checklists, supervision and review procedures and clearly defined internal control responsibilities.

We believe that these actions, as of September 30, 2012, provide the foundation for the effective remediation of our material weakness and the framework for a robust internal control system for the future. Our management has devoted significant time and resources to the evaluation and redesign of our internal control procedures and is currently committed to the comprehensive testing of these internal control procedures.

We believe that the corrective actions described above continue to strengthen our internal control over financial reporting. We expect to complete our internal control testing and any related refinement to our internal controls during the fourth quarter of 2012 and early first quarter of 2013.

We will continue to monitor the effectiveness of our remediation efforts of our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Except as it relates to the material weakness in internal control over financial reporting discussed above, there have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2012 that have materially affected, or are 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

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, 2011.

Risks related to our business

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. We obtained FDA clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We commenced offering our XT-8 system and our Warfarin Sensitivity Test in July 2008. We commenced offering our Cystic Fibrosis Genotyping Test in July 2009, our Thrombophilia Risk Test in April 2010 and our Respiratory Viral Panel Test in September 2012. Our net losses were approximately $17.4 million and $18.5 million for the nine months ended September 30, 2012 and 2011, respectively. Our net losses were approximately $24.0 million for the year ended December 31, 2011, $18.4 million for the year ended December 31, 2010 and $20.0 million in 2009. As of September 30, 2012, we had an accumulated deficit of $185.9 million. We will continue to incur significant expenses for the foreseeable future in connection with our commercial organization (sales and marketing), research and development and regulatory activities and maintaining our existing intellectual property, obtaining additional intellectual property rights and investing in corporate infrastructure. Although we believe that we will become cash flow positive, we cannot provide you 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 because the market for molecular diagnostic products is relatively new and rapidly evolving, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

We reported a material weakness in our internal control over financial reporting, and if we are unable to improve 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. We are devoting 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. This material weakness, or difficulties encountered in implementing new or improved controls or remediation, could prevent us from accurately reporting our financial results, result in material misstatements in our financial statements or cause us to fail to meet our reporting obligations.

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

We have a few large customers that generate a significant amount of our revenue. Our three largest customers accounted for 75% and 28% of our revenue in the third quarter of 2012 and for nine months ending September 30, 2012, respectively. In the third quarter of 2012, one specialty

diagnostic reference lab customer accounted for approximately 66% of our total revenues. Our significant customers are under contract; however, 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 contract. The loss of any significant customer or a significant reduction in the amount of product ordered by any such customer would adversely affect our revenue, results of operations, and cash flows.

Table of Contents

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

Our success depends on the market s confidence that we can provide reliable, high-quality diagnostic systems and tests. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. As a result, our reputation and the public image of our products or technologies will be 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.

If we experience a material defect or error, this could result in loss or delay of revenues, increased costs to produce our tests, delayed market acceptance, damaged reputation, diversion of development and management resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could materially harm our business, 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 have 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 fail to successfully expand the menu of diagnostic tests for our XT-8 system or effectively predict the types of tests our existing and target customers want.

We currently market four FDA-cleared diagnostic tests. In addition, we have several diagnostic tests in the research, development or design stage. Some hospital-based and reference laboratories may not consider adopting our XT-8 system until we offer a broader menu of diagnostic tests. Although we are developing additional tests to respond to the needs of these laboratories, we cannot guarantee that we will be able to license the appropriate technology, successfully develop, or obtain required regulatory clearances or approvals for additional tests, or do so in a manner that is cost-effective or timely. The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, in order to commercialize our products, we are required to undertake time consuming and costly development activities, including clinical studies for which the outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to successfully develop and commercialize additional diagnostic tests for use with our XT-8 system, our revenues and our ability to achieve profitability will be significantly impaired.

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

Demand for our Respiratory Viral Panel test can be seasonal based upon influenza outbreaks. Also, unanticipated changes in customer demand for our products may result in constraints or inefficiencies related to our manufacturing, sales force, implementation resources and administrative infrastructure. These constraints or inefficiencies may adversely affect us as a result of delays, lost potential product sales or loss of current or potential customers due to their dissatisfaction. Similarly, over-expansion or investments in anticipation of growth that does not materialize, or develops more slowly than we expect, could harm our financial results and result in overcapacity.

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

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

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

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

the expenses we incur for research and development required to maintain and improve our technology, including developing our next-generation molecular diagnostic system;

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

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

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

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

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

- companies developing and marketing multiplex molecular diagnostics systems, including Luminex Corporation; Nanosphere, Inc.; 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 laboratory-developed tests 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 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, more extensive manufacturing and distribution capabilities. The impact of these factors may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue.

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

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

We may not be successful in developing our NexGen system.

We are developing a sample-to-answer platform, the NexGen system. We are designing this system to integrate automated nucleic acid extraction and amplification with our eSensor technology to allow technicians to be able to place a patient sample into our test cartridge and obtain results with significantly reduced or no technician hands-on processing time. The development of the NexGen system is a complex process, and we may not be successful in completing the development of all the currently intended features and benefits of the system, which may limit its marketability. In addition, before commercializing the NexGen system we will be required to obtain regulatory approval for the system as well as each of the diagnostic tests to be used on the system, possibly including those tests that previously received approval for use with our XT-8 system. If we are unable to successfully develop and obtain regulatory approval for our NexGen system and related diagnostic tests, our business plan will be impaired. Additionally, prior to or upon release of our NexGen System, sales of our XT-8 system may decrease as customers migrate over to our newer technology.

Table of Contents

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

Our future success depends on the acceptance by our target customers, third-party payors and the medical community that our molecular diagnostic products are a reliable, 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 replace their current testing platforms and/or send-out tests, with our XT-8 system and related diagnostic tests. We must also continue to increase the number of available tests, and test sell-through, on our installed systems.

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 of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

Our success depends on our ability to service and support our products.

To the extent that we fail to maintain a high quality level of service and support for our products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could result in slower adoption rates and lower than anticipated utilization of our products which could have a material adverse effect on our business, financial condition and results of operations.

****Manufacturing risks and inefficiencies may adversely affect our ability to produce products; we have a sole source of supply for our XT-8 System.***

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. 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, we will be required to revalidate and may be required to resubmit a previously cleared product.

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.

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 and component assembly for our test cartridges. New XT-8 systems are manufactured by Leica Biosystems Melbourne Pty Ltd., our single source supplier that specializes in manufacturing of electronic and electromechanical devices for medical use. While we work closely with Leica Biosystems Melbourne Pty Ltd. to try to ensure continuity of supply while maintaining high quality and reliability, we cannot guarantee that these efforts will be successful. Should Leica Biosystems Melbourne Pty Ltd. become unable or unwilling to continue to meet our supply needs, we may experience delays in qualifying a new source or may not obtain as favorable pricing or other terms, any of which could harm our business, financial condition or results of operations.

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

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;

Table of Contents

- 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.

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

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

We have only produced our products in limited quantities, and we may experience problems in scaling our manufacturing operations, or 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 desired revenue growth. We may not be able to produce sufficient quantities 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.

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

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel. Our senior managers and other key employees can terminate their relationship with us at any time. We have a small number of senior managers, and the loss of services of any of these managers or our scientific or technical personnel could have a material adverse effect on our business, financial condition and results of operations. We do not maintain key-man life insurance on any of our employees.

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

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 significantly higher product revenues, 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 or 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.

Table of Contents

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

The markets for our products are characterized by rapidly changing technology, evolving industry standards, changes in customer needs, emerging competition and new product introductions. New technologies, techniques or products could emerge with similar or better performance or may be perceived as providing better value than our systems and related tests and could exert pricing pressures on our products. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers and prospective customers needs on a timely basis. We will need to respond to technological innovation in a rapidly changing industry and may not be able to maintain our technological advantages over emerging technologies in the future. If we fail to keep pace with emerging technologies, our systems and related tests will become uncompetitive and our market share will decline, which would harm our business, financial condition and results of operations.

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

Assuming we receive the applicable regulatory approvals, we intend to market our diagnostic products outside the United States through third-party distributors. These distributors may not commit the necessary resources to market and sell our products to 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, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which could harm our ability to expand into markets outside the United States.

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

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

- fluctuations in currency exchange rates;
- unexpected complexity and changing foreign regulatory requirements;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards;

increased financial accounting and reporting burdens and complexities;

hyperinflation, political, social and economic instability abroad, terrorist attacks and security concerns in general;

having to comply with a variety of U.S. laws, including the Foreign Corrupt Practices Act;

the imposition of restrictive trade policies, including export restrictions; and

conducting business in places where business practices and customs are unfamiliar and unknown

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

Guidelines, recommendations and studies published by various organizations can reduce the use of our products.

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

Table of Contents

government agencies or these other groups/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.

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

Our Respiratory Viral Panel Test and other tests that we develop in the future may have sales that fluctuate on a seasonal basis. As a result, our results of operations for any particular quarter may not accurately reflect full-year trends. For example, we expect volume of testing for our Respiratory Viral Panel test generally will decline during the spring and summer season and accelerate during the fall and winter season. As a result, comparison of our results from quarter-to-quarter may not accurately reflect trends or results for the full year.

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

We have limited marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on attracting customers for the XT-8 system, expanding the number of tests we offer, 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, national and regional reference laboratories; and
- the difficulty of establishing brand recognition and loyalty for our products.

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

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. The credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. 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, or development of products based on, 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.

If third-party payors increasingly restrict payments for healthcare expenses or fail to adequately pay for multi-analytic testing, we may experience reduced sales which would hurt our business and our business prospects.

Third-party payors, such as government entities and healthcare programs, health maintenance organizations and private insurers, are continually seeking to reduce healthcare expenses. The federal government has also recently reduced the funding for certain government-sponsored healthcare programs which has caused these third party payors to seek further reduction in medical expenses. The U.S. federal government passed comprehensive healthcare reform in the form of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, in 2010 and is considering revisions to this Act. The PPACA could further limit government and other third-party payor reimbursement, which, in turn, may lead to payor reduction in payments for healthcare services, including diagnostic tests provided by laboratories that purchase our products. These reductions may decrease demand for our products and the price we can charge.

Table of Contents

Increasingly, as a result of reforms and other pressures to reign in escalating healthcare costs, Medicare, Medicaid and other third-party payors are challenging the prices charged for medical services, including clinical diagnostic tests. They are also attempting to contain costs by limiting coverage and the reimbursement level of tests and other healthcare products. In addition, cost containment initiatives by governmental or educational entities or programs may reduce funding for genetic research and development activities and retard the growth of the genetic testing market. Without adequate coverage and reimbursement, consumer demand for tests could decrease. Decreased demand could cause our customers to reduce purchases or to cancel programs or development activities and could cause sales of our products to fall. In addition, decreased demand could place pressure on us to lower prices on these products or services, resulting in lower margins. Reduced sales or margins would adversely affect our business, profitability and business prospects.

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 incur the expense of manufacturing XT-8 systems well in advance of receiving sufficient revenues from test cartridges to recover our expenses. We also offer our XT-8 systems for sale. The amount of additional capital we may need to raise depends on the amount of our revenues from sales of reagents and test cartridges sold through these 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 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 resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Our operations are regulated and may require that environmental permits and approvals be issued by applicable government agencies. Compliance with environmental laws and regulations may be expensive and may impair our research, development and production efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

Our corporate structure may create tax inefficiencies.

As a result of our reorganization in 2010 and prior to the reorganization steps that took place in June 2011 (as described below), Osmetech plc was a wholly-owned subsidiary of GenMark and a controlled foreign corporation for U.S. federal income tax purposes. This organizational structure may have created inefficiencies, as certain types of income and 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, or 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. It is anticipated that the reorganization will 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 are eliminated on a go-forward basis, however, the reorganization may result in additional tax liabilities to the Company.

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

As of December 31, 2011, we had net operating loss carryforwards of approximately $96.5 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2031. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone

significant changes in stock ownership. We have determined that we have experienced multiple ownership changes under Section 382 of the Internal Revenue Code, as amended, or the Code. As of December 31, 2011, we estimated that approximately $39.0 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. The Company has not determined if there are any additional limitations on the utilization of its net operating losses as a result of any equity transactions in 2012, including the stock offering closed on June 26, 2012. The utilization of our net operating loss carryforwards may be further limited as a result of 2012 equity activity (inclusive of the June 26, 2012 stock offering). Our ability to use the current net operating loss carryforwards may also be

Table of Contents

limited by the issuance of common stock in the future. To the extent our use of net operating loss carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards. The Company currently has recorded a full valuation allowance against its deferred net assets.

We also had non-U.S. net operating loss carryforwards of approximately $30.4 million as of December 31, 2011. As a result of our offerings or other issuances of common stock in the future, the availability of such non-U.S. operating loss carryforwards may be limited, and our income may be subject to corporate tax earlier than it would if we were able to use non-U.S. net operating loss carryforwards, which would result in lower profits.

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.

Risks related to regulation

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

We are investing in the research and development of new diagnostic tests to expand our menu of testing options, as well as to develop our next-generation NexGen system, which we anticipate will reduce the need for sample preparation when using our system. Our products are subject to 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental entities prior to their marketing outside the United States. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510(k) clearance, pre-market approval or foreign regulatory approvals.

The 510(k) clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510(k) clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510(k) clearance or pre-market approval may never be obtained. There is no assurance that a 510(k) clearance or pre-market approval can be obtained within these timeframes, or at all. In addition, the FDA 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. Delays in receipt of, or failure to obtain, clearances or approvals for future products, including tests that are currently in design or development, would result in delayed, or no, realization of revenues from such products and in substantial additional costs, which could decrease our profitability. We have limited experience in filing FDA applications for 510(k) clearance and pre-market approval. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements once we have obtained clearance or approval for a product. There can be no assurance that we will obtain or maintain any required

clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

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

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

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

Table of Contents

cost effective; and

neither experimental nor investigational.

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

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

In the United States, the American Medical Association, or AMA, generally assigns specific billing codes for laboratory tests under a coding system known as Current Procedure Terminology, or CPT, codes, which are necessary for our customers to bill and receive reimbursement for our diagnostic tests. Once the CPT code is established, the Centers for Medicare & Medicaid Services, or CMS, responsible for implementing the Medicare program, in turn establishes payment levels and coverage rules under Medicare, and 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. In addition, payors have initiated efforts to develop a more specific set of billing codes for laboratory codes so that the particular laboratory test is more precisely identified. The AMA has established a number of new CPT codes for many molecular tests, including ours, intending to eliminate the stacking of existing codes and replacing them with test-specific codes. The AMA published approximately 100 new CPT codes that became effective as of January 2012, although CMS announced that it will not utilize these new codes for Medicare payment before January 2013. CMS also has not yet established payment amounts for these new codes, although currently, the agency has announced a process for making payment determinations. Other payors may develop their own payment schedules, separate from Medicare. At this time, the full effect of the coding and future payments associated with the codes is unclear.

In addition, some of our customers Medicare claims may be subject to policies issued by Palmetto GBA, the current Medicare Administrative Contractor for California, Nevada, Hawaii and certain U.S. territories. The Medicare contractor has recently issued a draft Local Coverage Decision that would affect coverage, coding and billing of many molecular diagnostic tests. If Palmetto finalizes the draft Local Coverage Determination, Palmetto would no longer cover any molecular diagnostic tests, including our tests, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto. Currently, laboratory providers may submit coverage determination requests to Palmetto for consideration and apply for a unique billing code for each test (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. In addition, effective June 1, 2012, Palmetto implemented its new Molecular Diagnostic Services Program, under which, among other things, laboratories must use newly-assigned billing codes specific to the test. These new billing codes currently are unique to this contractor and enable Palmetto to measure utilization and apply coverage determinations. Denial of coverage by Palmetto, or reimbursement at inadequate levels, could have a material adverse impact on market acceptance of our tests.

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. Under the statutory formula for Medicare clinical laboratory fee schedule amounts, for example, increases are made annually based on the Consumer Price Index for All Urban Consumers, or CPI-U, as of June 30 for the previous 12-month period. From 2004 through 2008, Congress eliminated the CPI-U update in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, mandated a 0.5% cut to the CPI-U. Accordingly, the update for 2009 was reduced to 4.5% and -1.9% for 2010. In March 2010, the President signed into law PPACA, which, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. The PPACA replaced the 0.5% cut enacted by MIPPA with a productivity adjustment that will reduce the CPI update in payments for clinical laboratory tests. For 2011 and 2012, the productivity adjustment was -1.2%. In addition, the PPACA includes a separate 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. On February 22,

31

Table of Contents

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 for and reimbursement available for our products, which in turn, could harm 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.

We are subject to evolving legislative, judicial and ethical standards on use of technology and biotechnology.

The adoption of genetic testing is occurring within the broader context of a myriad of decisions related to genetic patenting and genotyping. Issues associated with health insurance, data access, intellectual property protection, national and international legislative initiatives and other variables may have a significant impact on the wide spread adoption of genetic testing or on specific segments or tests within the genetic testing market, including the adoption of our NexGen system and other of our products that are currently in the development and design stage.

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

Our manufacturing processes and facilities, and those of some of our contract manufacturers, are required to comply with the federal Quality System Regulation, or 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;
- the FDA s refusal to grant pending future clearance or pre-market approval for our products;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;

warning letters;

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

criminal prosecution.

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

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

The use of our diagnostic products by our customers is also affected by the Clinical Laboratory Improvement Amendments, or CLIA, and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance and quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories from using some or all of our diagnostic products.

Table of Contents

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, in the future, the FDA may require more burdensome premarket approval of our system or diagnostic tests rather than the 510(k) clearance process we have used to date and anticipate primarily using in the future. In addition, FDA 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. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would harm our business, financial condition and results of operations.

Federal and state governments in the United States are also undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted the PPACA. While the PPACA involves expanding coverage to more individuals, it includes new regulatory mandates and other measures designed to constrain medical costs. The PPACA also imposes, in addition to those provisions identified above in the Risk Factor entitled If third-party payors do not reimburse our customers for the use of our clinical diagnostic products or if reimbursement levels are set too low for us to sell our products at a profit, our ability to sell our products and our results of operations will be harmed, a provision for 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 Federal Food, Drug and Cosmetic Act of 1938, as amended, and intended for use by humans, with limited exclusions for devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we expect to begin paying the tax in 2013. Complying with PPACA could significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

A number of states and other parties have challenged the constitutionality of certain provisions of PPACA, in particular the mandate that all individuals must obtain insurance, and many of these court challenges are still pending final adjudication in several jurisdictions. A ruling from the U.S. Supreme Court on June 28, 2012 found the law to be constitutional. At this time, it remains unclear whether there will be any changes made to certain provisions of PPACA or its entirety. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 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 PPACA and the Budget Control Act is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the medical device industry generally.

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. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. If our marketing, sales or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which could likely harm on our business, financial condition and results of operations.

Beginning in 2013, the PPACA also imposes new reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. On December 14, 2011, CMS released its proposed rule implementing

Table of Contents

these provisions, providing further clarification to ambiguous or unclear statutory language and providing instructions for manufacturers to comply with such requirements. In addition, CMS estimates that approximately 1,000 device and medical supply companies will be required to comply with the disclosure requirements. 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 result of operations.

Risks related to our intellectual property

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

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

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

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

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

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

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

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

Table of Contents

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

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

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, 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, and 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 PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

There is a substantial amount of litigation involving patent and other intellectual property rights in the medical device, biotechnology and pharmaceutical industries generally. If a third party claims that we or any collaborator infringes its intellectual property rights, we may face a number of issues, including, but not limited to:

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

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

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

From time to time we may become engaged in litigation with third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. These third parties and others who may in the future threaten us with such litigation, are or may be better capitalized and have more resources than us. In addition, in order to commercialize certain new or existing tests , we may be required to license certain biomarkers or risk that a third party may claim that the use of certain biomarkers in our tests

infringes their intellectual property rights. We have received correspondence bringing to our attention certain patent rights held by third parties and offering to discuss licensing terms to the patents. Some of these letters relate to patents that are important to our products. Independently, we have also identified patents held by third parties that cover one or more of our products or planned products. Although we have taken licenses to numerous such third-party patents, we have also declined to license certain patents in instances where we do not believe our existing products infringe valid claims.

If 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 100 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

Table of Contents

claimed priority date. Our issued and exclusively licensed patents will expire between 2013 and 2021 or later, with several of our pending applications having the potential to mature into patents that might expire in 2027, 2028 and 2029. 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.

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

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

- others may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents;
- we may not be able to identify potential infringers of our technology due in part to the large number of competitors in the field;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;
- our issued patents may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges by third parties;
- the claims of our issued patents or patent applications when issued may not cover our device or product candidates;
- there may be dominating patents relevant to our product candidates of which we are not aware;

there may be prior public disclosures that could invalidate our inventions or parts of our inventions of which we are not aware;

the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States; and

we may not develop additional proprietary technologies that are patentable.

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

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

Table of Contents

The U.S. Government has certain rights to use and disclose some of the intellectual property that we license and could exclusively license it to a third party if we fail to achieve practical application of the intellectual property.

Aspects of the technology licensed by us under agreements with third party licensors may be subject to certain government rights. Government rights in inventions conceived or reduced to practice under a government-funded program may include a non-exclusive, royalty-free worldwide license to practice such inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors (as applicable) to grant licenses which would be exclusive under any of such inventions to a third party if they determine that: (1) adequate steps have not been taken to commercialize such inventions in a particular field of use; (2) such action is necessary to meet public health or safety needs; or (3) such action is necessary to meet requirements for public use under federal regulations. Further, the government rights include the right to use and disclose, without limitation, technical data relating to licensed technology that was developed in whole or in part at government expense. At least one of our technology license agreements contains a provision recognizing these government rights.

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

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

Risks related to ownership of our common stock

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

The market price of our common stock may be subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this Risk Factors section and other factors, including:

- fluctuations in our operating results or the operating results of our competitors;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;

success of competitive products and services;

changes in market valuations or earnings of our competitors;

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

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

the timing and outcome of regulatory reviews and approvals of our products;

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

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

Table of Contents

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

As of September 30, 2012, we had 32,666,597 shares of our common stock outstanding. Sales of a number of shares of common stock in the public market, or the expectation of such sales, could cause the market price of our common stock to decline. In addition, our 2010 Equity Incentive Plan provides for annual increases in the number of shares available for issuance under the plan, which may, among other things, result in dilution of the price of our common stock. We may also sell additional common stock in subsequent public offerings, which may adversely affect the market price of our common stock.

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

As a public company in the United States, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Our first report on compliance with Section 404 is in connection with our financial statements for the fiscal year ending December 31, 2011. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or the SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. If we or our auditors were unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities such as the SEC or 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 and the price of our common stock and our ability to access the capital markets.

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

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

We do not expect to declare any dividends on our common stock in the foreseeable future.

We currently intend to invest our future earnings, if any, to fund the development and growth of our business. In addition, pursuant to our Loan and Security Agreement with Square 1 Bank, we are restricted from paying any dividends. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, future prospects, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt agreements we may enter into and other factors our Board of Directors may deem relevant. Consequently, stockholders may need to rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not purchase our common stock.

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;

Table of Contents

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.

Table of Contents

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

Unregistered Sales of Equity Securities

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs
July 1 - 31, 2012	33,610	$ 5.00		
August 1 - 31, 2012	504	$ 6.09		
September 1 - 30, 2012	30,287	$ 8.44		
July 1, 2012 through September 30, 2012	64,401	$ 6.58		

(1) Through our stock incentive plans, 5,591 shares were delivered to us by our employees to satisfy their tax withholding requirements upon vesting of restricted stock for the quarter ended September 30, 2012.

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: November 8, 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.

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).
10.31**	Development Collaboration and License Agreement, dated July 26, 2012, by and between Advanced Liquid Logic, Inc. and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc.
10.32**	XT-8 Instrument Supply Agreement, dated August 3, 2012, by and between Leica Biosystems Melbourne Pty Ltd and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc.
10.33**	Reagent Rental Agreement, dated September 27, 2012, by and between Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. and Customer.
10.34	Separation Agreement and General Release, dated August 21, 2012, by and between Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc. and Matthew Cohen.
10.35	Third Amendment to Lease agreement dated August 28, 2012, by and between The Campus Carlsbad, LLC and Clinical Micro Sensors, Inc. dba GenMark Diagnostics, Inc.
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.

** Confidential Treatment Requested
Management Compensation Plan