GenMark Diagnostics, Inc.
Form 10-Q
October 30, 2014
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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, 2014
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 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 October 28, 2014, was 41,734,301.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	September 30, 2014	December 31, 2013
Current assets		
Cash and cash equivalents	$25,658	$35,723
Marketable securities	53,590	69,866
Accounts receivable, net of allowances of $2,702 and $2,736, respectively	2,709	2,859
Inventories	1,532	2,102
Prepaid expenses and other current assets	1,229	552
Total current assets	84,718	111,102
Property and equipment, net	10,190	8,591
Intangible assets, net	1,934	1,197
Restricted cash	758	758
Other long-term assets	118	106
Total assets	$97,718	$121,754
Current liabilities		
Accounts payable	$3,307	$3,863
Accrued compensation	5,132	3,375
Other current liabilities	3,113	2,999
Total current liabilities	11,552	10,237
Long-term liabilities		
Deferred rent	1,488	1,601
Other non-current liabilities	114	748
Total liabilities	13,154	12,586
Stockholders' equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 41,726 and 41,520 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	4	4
Additional paid-in capital	338,415	333,363
Accumulated deficit	(253,859)	(224,209)
Accumulated other comprehensive income	4	10
Total stockholders' equity	84,564	109,168
Total liabilities and stockholders' equity	$97,718	$121,754

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue				
Product revenue	$6,233	$4,521	$20,593	$20,627
License and other revenue	67	116	175	325
Total revenue	6,300	4,637	20,768	20,952
Cost of revenue	2,692	4,138	9,591	12,373
Gross profit	3,608	499	11,177	8,579
Operating expenses				
Sales and marketing	3,159	4,916	9,516	9,830
General and administrative	2,817	2,476	8,760	7,572
Research and development	7,904	5,398	23,297	15,786
Total operating expenses	13,880	12,790	41,573	33,188
Loss from operations	(10,272)	(12,291)	(30,396)	(24,609)
Other income (expense)				
Interest income	228	203	783	413
Interest expense	(14)	(3)	(18)	(17)
Other income (expense)	(216)	1,297	(611)	1,232
Total other income (expense)	(2)	1,497	154	1,628
Loss before provision for income taxes	(10,274)	(10,794)	(30,242)	(22,981)
Income tax expense (benefit)	(616)	23	(591)	30
Net loss	$(9,658)	$(10,817)	$(29,651)	$(23,011)
Net loss per share, basic and diluted	$(0.23)	$(0.30)	$(0.72)	$(0.69)
Weighted average number of shares outstanding, basic and diluted	41,446	35,987	41,273	33,331
Other comprehensive loss				
Net loss	$(9,658)	$(10,817)	$(29,651)	$(23,011)
Net unrealized gains (losses) on marketable securities, net of tax	(3)	21	6	12
Comprehensive loss	$(9,661)	$(10,796)	$(29,645)	$(22,999)

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Nine Months Ended September 30,	
	2014	2013
Operating activities		
Net loss	$(29,651)	$(23,011)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,870	1,912
Amortization of premiums on marketable securities	577	133
Stock-based compensation	4,478	2,697
Provision for bad debt	—	2,720
Non-cash inventory adjustments	517	675
Changes in operating assets and liabilities:		
Accounts receivable	151	(1,885)
Inventories	209	(216)
Prepaid expenses and other assets	(691)	(263)
Accounts payable	(318)	570
Accrued compensation	1,757	29
Other liabilities	(1,131)	(861)
Net cash used in operating activities	(22,232)	(17,500)
Investing activities		
Change in restricted cash	—	585
Payments for intellectual property licenses	(350)	(888)
Purchases of property and equipment	(3,699)	(3,273)
Purchases of marketable securities	(28,054)	(52,841)
Proceeds from sales of marketable securities	7,497	4,250
Maturities of marketable securities	36,250	800
Net cash provided by (used in) investing activities	11,644	(51,367)
Financing activities		
Proceeds from issuance of common stock	373	86,247
Costs incurred in conjunction with public offering	—	(5,180)
Principal repayment of borrowings	(51)	(706)
Proceeds from borrowings	—	166
Proceeds from stock option exercises	201	364
Net cash provided by financing activities	523	80,891
Net increase (decrease) in cash and cash equivalents	(10,065)	12,024
Cash and cash equivalents at beginning of period	35,723	51,250
Cash and cash equivalents at end of period	$25,658	$63,274
Non-cash investing and financing activities		
Transfer of instruments from property and equipment to inventory	$156	$431
Property and equipment costs included in accounts payable	$364	$308
Intellectual property acquisitions included in other current liabilities	$550	$556
Supplemental cash flow disclosures		
Cash paid for income taxes, net	$27	$8
Cash received for interest	$783	$413
Cash paid for interest	$18	$17

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

GenMark Diagnostics, Inc., the Company or GenMark, was formed by Osmetech plc, or Osmetech, as a Delaware corporation in February 2010, and had no operations prior to its initial public offering, or the IPO, which was completed in June 2010. Immediately prior to the closing of the IPO, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of: (i) the issuance of common stock of GenMark to the former shareholders of Osmetech; and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure. The liquidation of Osmetech was completed in the fourth quarter of 2013.

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

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

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

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

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

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

Basis of Presentation

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 had an accumulated deficit of $253,859,000 as of September 30, 2014. Management expects operating losses to continue for the foreseeable future. The Company's ability to transition to profitable operations is dependent upon achieving a level of revenues adequate to support its cost structure through expanding its product offerings and consequently increasing its product revenues. Cash, cash equivalents and marketable securities as of September 30, 2014 were $79,248,000. The Company has prepared cash flow forecasts which indicate, based on the Company’s current cash resources available, that the Company will have sufficient resources to fund its business for at least the next 12 months.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, and applicable regulations of the U.S. Securities and Exchange Commission, or the SEC, and should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the SEC on March 11, 2014. These unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. These adjustments are of a normal, recurring nature. Interim period operating results may not be indicative of the operating results for the full year or any future period.

Segment Information

The Company currently operates in one reportable business segment, which encompasses the development, manufacturing, sales and support of instruments and 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.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or the FASB, or other standard setting bodies that the Company adopts as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial condition or results of operations upon adoption.

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Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash on deposit with banks, money market instruments and certificates of deposit with original maturities of three months or less at the date of purchase. Marketable securities consist of certificates of deposit, corporate notes, commercial paper, U.S. government treasury securities and securities of government-sponsored entities that mature in greater than three months. Marketable securities are accounted for as "available-for-sale" with the carrying amounts reported in the balance sheets stated at cost, which approximates their fair market value, with unrealized gains and losses, if any, reported as a separate component of stockholders' equity and included in comprehensive loss.

Receivables

Accounts receivable consist of amounts due to the Company for sales to customers and are recorded net of an allowance for doubtful accounts. The allowance for doubtful accounts is determined based on an assessment of the collectability of specific customer accounts, the aging of accounts receivable, and a reserve for unknown items based upon the Company’s historical experience.

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and included $758,000 as of September 30, 2014, which is held as security for the Company’s letter of credit with Banc of California related to the Company's facility lease.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes thereto. The Company’s significant estimates included in the preparation of the financial statements are related to accounts receivable, inventories, property and equipment, intangible assets, employee related compensation accruals, warranty liabilities, tax valuation accounts and stock-based compensation. Actual results could differ from those estimates.

Product Warranties

The Company generally offers a one-year warranty for its systems sold to customers and typically up to a sixty day warranty for consumables. Factors that affect the Company’s warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary.

Intangible Assets

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

Impairment of Long-Lived Assets

The Company assesses the recoverability of long-lived assets, including intangible assets, by periodically evaluating the carrying value whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If impairment is indicated, the Company writes down the carrying value of the asset to its estimated fair value. This fair value is primarily determined based on estimated discounted cash flows.

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 value, as needed. This write down is based on management's review 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.

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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 identified below. Repair and maintenance costs are expensed as incurred.

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

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 net 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 related to uncertain tax positions as a component of income tax expense.

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

2. Stock-Based Compensation

The Company recognizes stock-based compensation expense related to stock options, restricted stock awards and restricted stock units granted to employees and directors in exchange for services and employee stock purchases related to the Company's 2013 Employee Stock Purchase Plan, or the ESPP. Stock-based compensation expense is based on the fair value of the applicable award utilizing various assumptions regarding the underlying attributes of the award. Stock-based compensation expense is recorded in cost of sales, sales and marketing, research and development, and general and administration expenses based on the employee's respective function.

The estimated fair value of stock options granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on a straight-line basis to reflect vesting as it occurs. The expense is derived from the Black-Scholes Option Pricing Model that uses several judgment-based variables to calculate the expense. The inputs include the expected term of the stock option, the expected volatility and other factors.

- Expected Term. Expected term represents the period that the stock-based awards are expected to be outstanding and is determined by using the simplified method.
- Expected Volatility. Expected volatility represents the volatility in the Company's estimated stock price over the expected term of the stock option and is determined by review of the Company's and similar companies' historical experience.
- Expected Dividend. The Black-Scholes Option Pricing Model calls for a single expected dividend yield as an input. The Company assumed no dividends as it has never paid dividends and has no current plans to do so.
- Risk-Free Interest Rate. The risk-free interest rate used in the Black-Scholes Option Pricing Model is based on published U.S. Treasury rates in effect at the time of grant for periods corresponding with the expected term of the option.

The compensation expense related to the grant of restricted stock awards or units is calculated as the fair market value of the stock on the grant date as further adjusted to reflect expected forfeitures.

Employee participation in the Company's 2010 Equity Incentive Plan, or the 2010 Plan, is at the discretion of the Compensation Committee of the Board of Directors of the Company. All stock options granted under the 2010 Plan are exercisable at a per share price equal to the closing quoted market price of a share of the Company’s stock on the NASDAQ Global Market on the grant date and generally vest over a period of between one and four years. Stock options are generally exercisable for a period of up to 10 years after grant and are typically forfeited if employment is terminated before the options vest. As of September 30, 2014, there were 451,392 shares available for future grant under the 2010 Plan. Each grant of stock options, restricted stock awards and restricted stock units reduces the number of shares available for grant under the 2010 Plan.

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The following table summarizes stock option activity during the nine months ended September 30, 2014:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2013	1,821,216	$6.89	6.74	$7,996,581
Granted	938,416	11.91		
Exercised	(41,670)	4.82		
Cancelled	(171,015)	9.37		
Outstanding as of September 30, 2014	2,546,947	$8.61	7.27	$4,390,518
Exercisable as of September 30, 2014	1,276,813	$6.14	5.89	$3,945,518

The following table presents the weighted average assumptions used by the Company to estimate the fair value of stock options granted, as well as the resulting weighted average fair values for the nine months ended September 30, 2014:

	Nine Months Ended September 30,			
	2014		2013	
Expected volatility	69	%	74	%
Expected life (years)	6.08		6.08	
Risk free interest rate	1.82	%	1.14	%
Expected dividend yield	—	%	—	%
Weighted average fair value	$7.47		$7.28	

In March 2013, the Company transitioned to granting restricted stock units under the 2010 Plan in lieu of granting restricted stock awards. The Company's restricted stock award and restricted stock unit activity for the nine months ended September 30, 2014 was as follows:

	Restricted Stock Awards		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2013	508,606	$4.54	474,847	$11.51
Granted	—	—	517,419	11.71
Vested	(250,207)	4.36	(162,134)	12.02
Cancelled or expired	(38,359)	5.57	(84,531)	11.69
Unvested as of September 30, 2014	220,040	$4.56	745,601	$11.52

As of September 30, 2014, there was $905,000 of unrecognized compensation cost related to unvested restricted stock awards, which is expected to be recognized over a weighted average period of 1.42 years. The total fair value of restricted stock awards that vested during the nine months ended September 30, 2014 and 2013 was $2,978,000 and $1,287,000, respectively. As of September 30, 2014, there was $7,061,000 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.85 years. The total fair value of restricted stock units that vested during the nine months ended September 30, 2014 and 2013 was $1,791,000 and $39,000, respectively.

Restricted stock awards or units may be granted at the discretion of the Compensation Committee of the Board of Directors under the 2010 Plan in connection with the hiring or retention of personnel and are subject to certain conditions. Restrictions expire at certain dates in accordance with specific provisions in the applicable award agreement. During the nine months ended September 30, 2014 and 2013, stock compensation expense for restricted

stock units and awards was $2,453,000 and $1,338,000, respectively.

The Company issued performance-based restricted stock units in March 2014. The vesting and issuance of Company stock pursuant to these awards depends on obtaining regulatory clearance of various products within a defined timeline. Stock-based compensation expense for performance-based awards is recognized when it is probable that the applicable performance criteria

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will be satisfied. The probability of achieving the relevant performance criteria is evaluated on a quarterly basis. During the nine months ended September 30, 2014, expense of $89,000 was recognized, based on the probability of achieving the applicable performance criteria under these awards. As of September 30, 2014, there was $44,000 of unrecognized stock-based compensation expense related to these awards.

Employee Stock Purchase Plan

Following the adoption of the ESPP by the Company's Board of Directors in March 2013, the Company's stockholders approved the ESPP in May 2013 at the Company's Annual Meeting of Stockholders. A total of 650,000 shares of the Company's common stock were originally reserved for issuance under the ESPP, which permits eligible employees to purchase common stock at a discount through payroll deductions.

The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors; provided that no offering period may exceed 27 months. Employees may invest up to 10% of their qualifying gross compensation through payroll deductions. In no event may an employee purchase more than 1,500 shares of common stock during any six-month offering period. As of September 30, 2014, there were 576,741 shares of common stock available for issuance under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation, therefore, stock-based compensation expense has been recorded during the nine months ended September 30, 2014.

3. Net Loss per Common Share

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

The computations of diluted net loss per share for the three and nine month periods ended September 30, 2014 and 2013 did not include the effects of the following stock options and restricted stock awards which were outstanding as of the end of each period because the inclusion of these securities would have been anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Options outstanding to purchase common stock	2,547	1,830	2,547	1,830
Unvested restricted stock	1,009	1,038	1,009	1,038
Total	3,556	2,868	3,556	2,868

4. Inventories

Inventory on hand as of September 30, 2014 and December 31, 2013 was comprised of the following (in thousands):

	September 30, 2014	December 31, 2013
Raw materials	$496	$713
Work-in-process	377	437
Finished goods	659	952
	$1,532	$2,102

5. Property and Equipment, net

Property and equipment as of September 30, 2014 and December 31, 2013 was comprised of the following (in thousands):

	September 30, 2014	December 31, 2013
Property and equipment — at cost:		
Machinery and laboratory equipment	$5,550	$3,260
Instruments	7,099	7,013
Office equipment	1,455	1,325
Leasehold improvements	4,179	3,755
Total property and equipment — at cost	18,283	15,353
Less: accumulated depreciation	(8,093)	(6,762)
Property and equipment, net	$10,190	$8,591

Depreciation expense was $638,000 and $791,000 for the three months ended September 30, 2014 and 2013, respectively, and was $1,707,000 and $1,684,000 for the nine months ended September 30, 2014 and 2013, respectively.

6. Intangible Assets, net

Intangible assets as of September 30, 2014 and December 31, 2013 were comprised of the following (in thousands):

	September 30, 2014			December 31, 2013		
	Gross carrying amount	Accumulated amortization	Net carrying amount	Gross carrying amount	Accumulated amortization	Net carrying amount
Intellectual property licenses	$2,750	(816)	$1,934	$2,409	(1,212)	$1,197

Intellectual property licenses have a weighted average remaining amortization period of 7.61 years as of September 30, 2014. Amortization expense for the licenses was $64,000 and $84,000 for the three months ended September 30, 2014 and 2013, respectively, and was $163,000 and $228,000 for the nine months ended September 30, 2014 and 2013, respectively. Estimated future amortization expense for these licenses is as follows (in thousands):

Fiscal Years Ending	Future Amortization Expense
Remaining in 2014	$64
2015	257
2016	254
2017	254
2018	254
Thereafter	851
Total	$1,934

7. Loan Payable

In September 2012, the Company entered into a term loan with Banc of California, consisting of the following two loans.

1) The Company increased the letter of credit provided to its landlord of its Carlsbad, California facility to $758,000 from the previous letter of credit of $500,000. The increase in the letter of credit was required by the Company’s landlord in connection with the Company’s lease of additional space at this facility. This letter of credit was secured with $758,000 of restricted cash as of September 30, 2014.

2) The Company obtained a variable rate term loan from Banc of California in the amount of $836,000 with an initial interest rate of 3.75% that expired in July 2013. As of December 31, 2013, the Company had repaid all outstanding amounts under this loan.

8. Leases

The Company has operating and capital lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged under these arrangements was $268,000 and $292,000 for the three months ended September 30, 2014 and 2013, respectively, and $858,000 and $757,000 for the nine months ended September 30, 2014 and

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2013, respectively. Pursuant to the Company's lease agreements, a portion of the monthly rent has been deferred. The balance of deferred rent as of September 30, 2014 and December 31, 2013 was $1,636,000 and $1,725,000, respectively.

As of September 30, 2014, the future minimum lease payments required over the next five years under the Company's lease arrangements are as follows (in thousands):

Fiscal Years Ending	Future Minimum Lease Payments
Remaining in 2014	$267
2015	1,084
2016	1,116
2017	1,123
2018	1,156
Thereafter	3,044
Total	$7,790

9. Fair Value of Financial Instruments

The carrying amounts of financial instruments, such as cash equivalents, restricted cash, accounts receivable, and accounts payable approximate the related fair values due to the short-term maturities of these instruments.

The Company uses a fair value hierarchy with three levels of inputs, of which the first two are considered observable and
the last unobservable, to measure fair value:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs, other than Level 1, that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table presents the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market funds (cash equivalents)	$19,805	$—	$—	$19,805
Corporate notes and bonds	—	24,265	—	24,265
U.S. government and agency securities	—	26,826	—	26,826
Commercial paper	—	2,499	—	2,499
Total	$19,805	$53,590	$—	$73,395

	December 31, 2013			
	Quoted Prices in Active Markets for	Significant Other Observable	Significant Unobservable Inputs	Total

	Identical Assets (Level 1)	Inputs (Level 2)	(Level 3)	
Money market funds (cash equivalents)	$10,020	$—	$ —	$10,020
Corporate notes and bonds	—	22,954	—	22,954
U.S. government and agency securities	—	43,115	—	43,115
Commercial paper	—	3,797	—	3,797
Total	$10,020	$69,866	$ —	$79,886

Level 2 marketable securities are priced using quoted market prices for similar instruments or nonbinding market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs.

10. Marketable Securities

The following table summarizes the Company's marketable securities as of September 30, 2014 and December 31, 2013 (in thousands):

September 30, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$24,280	$6	$(21)	$24,265
U.S. government and agency securities	26,821	8	(3)	26,826
Commercial paper	2,499	—	—	2,499
Total	$53,600	$14	$(24)	$53,590

December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$22,949	$12	$(7)	$22,954
U.S. government and agency securities	43,124	3	(12)	43,115
Commercial paper	3,797	—	—	3,797
Total	$69,870	$15	$(19)	$69,866

The following table summarizes the maturities of the Company's marketable securities as of September 30, 2014 (in thousands):

	Amortized Cost	Estimated Fair Value
Due in one year or less	$37,801	$37,806
Due after one year through two years	15,799	15,784
Total	$53,600	$53,590

11. Income Taxes

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

As of September 30, 2014, the Company 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. Due to the Company's losses, it only records a tax provision or benefit related to uncertain tax positions and related interest and minimum tax payments or refunds. The Company recorded an income tax benefit of $591,000 for the nine months ended September 30, 2014 and income tax expense of $30,000 for the nine months ended September 30, 2013.

During the third quarter, the Company reduced the amount of unrecognized tax benefits associated with uncertain tax positions by $610,000, including interest and penalties of $228,000, as a result of the expiration of applicable statute of limitations.

The Company is subject to taxation in the United States and in various state jurisdictions. In previous years, the Company was also subject to income taxes in the United Kingdom based upon its legacy operations. As of September 30, 2014, the Company's tax years after 2008 are subject to examination by the U.K. tax authorities. Except

for net operating losses generated in prior years carrying forward to the current year, as of September 30, 2014, the Company is no longer subject to U.S. federal, state, or local examinations for years before 2009.

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 for the nine months ended September 30, 2014 and the notes thereto included in Part I, Item 1 of this Quarterly Report, 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, 2013, included in our Annual Report on Form 10-K for the year ended December 31, 2013.

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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management, including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as "expect," "anticipate," "target," "project," "believe," "goals," "estimate," "potential," "pre "may," "will," "might," "could," "intend," variations of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in 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" in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 11, 2014. We assume no obligation to update these forward looking statements to reflect future events or circumstances.

Overview

GenMark Diagnostics, Inc., or GenMark, was formed by Osmetech plc, or Osmetech, as a Delaware corporation in February 2010. GenMark had no operations prior to its initial public offering (IPO), which was completed in June 2010. Immediately prior to the closing of the IPO, GenMark acquired all of the outstanding ordinary shares of Osmetech in a reorganization under the applicable laws of the United Kingdom. As a result of the reorganization, all of the issued ordinary shares in Osmetech were cancelled in consideration of: (i) the issuance of common stock of GenMark to the former shareholders of Osmetech; and (ii) the issuance of new shares in Osmetech to GenMark. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term incentive awards and all warrants issued by Osmetech were exchanged for options and warrants exercisable for the common stock of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure. The liquidation of Osmetech was completed in the fourth quarter of 2013.

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 on our XT-8 system of up to 72 distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the U.S. Food and Drug Administration (FDA) and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within approximately 30 minutes of receipt of an extracted and amplified nucleic acid sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports up to 24 independent test cartridges, each of which can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are hospitals and reference laboratories. As of September 30, 2014, we had an installed base of 502 XT-8 analyzers, or placements, with our customers.

Since inception, we have incurred net losses from operations each year, and we expect to continue to incur losses for the foreseeable future. Our net losses for the nine months ended September 30, 2014 and 2013 were approximately $29,651,000 and $23,011,000, respectively. As of September 30, 2014, we had an accumulated deficit of $253,859,000. Our operations to date have been funded principally through sales of capital stock, borrowings and cash from operations. We expect to incur increasing expenses over the next several years, principally to develop our ePlex™ instrument system and additional diagnostic tests, as well as to further increase our capability to manufacture, sell and market our products.

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Our Products and Technology

We have developed eight tests for use with our XT-8 system. 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, which simultaneously detects and differentiates 14 clinically relevant viruses from patients with influenza-like illnesses. Our eSensor® technology has demonstrated 100% accuracy in clinical studies compared to DNA sequencing and other standards in our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test and our Thrombophilia Risk Test. We have also developed two Hepatitis C virus (HCV) genotyping tests, a 3A4/3A5 genotyping test and a 2C19 genotyping test, versions of which are available for research use only (RUO).

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

We are currently developing seven assays for our ePlex™ system, which include gram-positive and gram-negative bacterial identification panels, a respiratory panel (RP), a gastrointestinal (GI) panel, an HCV genotyping panel, a central nervous system (CNS) infection panel, and a fungal infection panel. We intend to continue investing in our ePlex™ system and its related test menu for the foreseeable future. We currently expect to complete the development of our complete ePlex™ system by the end of 2014 and launch the system in Europe shortly thereafter. In addition, we expect to launch the ePlex™ system in the United States in the second half of 2015.

Revenue

Revenue from operations includes product sales, principally of our diagnostic tests for use with our XT-8 system. We primarily place our XT-8 system with customers through a reagent rental agreement, under which we retain title to the instrument and customers commit to purchasing minimum quantities of reagents and test cartridges over a period of one to three years. We also offer our XT-8 system for sale.

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

Our growth plans in 2014 focus primarily on reagent rental agreements and sales of our current XT-8 system. Our future growth plans also focus on sales and placements of our ePlex™ system that is currently under development. We do not anticipate any significant sales of our ePlex™ system in 2014. We plan to continue expanding our base of XT-8 customers and systems as well as test utilization among our customers. We expect sales of our XT-8 test cartridges to be our primary source of revenue during 2014 and until the commercial launch of our ePlex™ system and related tests.

Cost of Revenues

Cost of revenues includes the cost of materials, direct labor and manufacturing overhead costs used in the manufacture of our consumable test kits for our XT-8 system, including royalties on product sales. Cost of revenues also includes depreciation on revenue generating systems that have been placed with our customers under a reagent rental agreement, amortization of licenses related to our products and other costs such as warranty and customer technical support. We manufacture our test cartridges in our facility and have invested in significant capacity for expansion. This potential underutilized capacity may result in a high cost of revenues relative to revenue, if manufacturing volumes are not able to fully absorb operating costs. Our XT-8 systems are procured from a contract manufacturer and are generally capitalized as fixed assets and depreciated on a straight-line basis over their useful life as a charge to cost of revenues. We expect our cost of revenues to increase as we place additional XT-8 systems and manufacture and sell our menu of accompanying diagnostic tests; however, we expect our gross margins to increase as manufacturing

efficiencies, improved procurement practices, instrument reliability increases and other improvements decrease costs as a percentage of revenues.

Sales and Marketing Expenses

Sales and marketing expenses include costs associated with our direct sales force, sales management, marketing, technical support and business development activities. These expenses primarily consist of salaries, commissions, benefits, stock-based compensation, travel, advertising, promotions, samples and trade shows. We expect sales and marketing costs to increase as we scale-up our domestic and international commercial efforts to expand our customer base.

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Research and Development Expenses

Research and development expenses primarily include expenses related to the development of our ePlex™ instrument and related test menu. These expenses also include certain clinical study expenses incurred in preparation for FDA clearance for these products, intellectual property prosecution and maintenance costs, and quality assurance expenses. These expenses primarily consist of salaries, benefits, stock-based compensation costs, outside design and consulting services, laboratory supplies, contract research organization expenses, clinical study supplies and facility costs. We expense all research and development costs in the periods in which they are incurred. We expect research and development costs to increase as we complete development of our ePlex™ system and invest in expanding its related test menu.

General and Administrative Expenses

Our general and administrative expenses include expenses related to our executive, accounting and finance, compliance, information technology, legal, facilities, human resource, administrative and investor relations activities. These expenses consist primarily of salaries, benefits, stock-based compensation costs, independent auditor costs, legal fees, consultants, travel, insurance, and public company expenses, such as stock transfer agent fees and listing fees for NASDAQ.

Foreign Exchange Gains and Losses

Transactions in currencies other than our functional currency are translated at the prevailing rates on the dates of the applicable transaction. Foreign exchange gains and losses arise from differences in exchange rates during the period between the date a transaction denominated in a foreign currency is consummated and the date on which it is settled or translated.

Interest Income and Interest Expense

Interest income includes interest earned on our cash, cash equivalents and marketable securities. Interest expense represents interest incurred on our loan payable and on other liabilities.

Provision for Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including historical levels of income, expectations and risks associated with estimates of future taxable income, and ongoing prudent and feasible tax planning strategies in assessing the need for our valuation allowance. If it is more likely than not that we will not recover our deferred tax assets, we will increase our provision for income taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable.

Our income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential adjustments and adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Results of Operations — Three and nine months ended September 30, 2014 compared to the three and nine months ended September 30, 2013 (in thousands):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Revenue	$6,300	$4,637	$1,663	36 %	$20,768	$20,952	$(184)	(1)%

Our revenue consists primarily of revenue from the sale of reagents and test cartridges (consumables) with a small component resulting from our sale of instruments and other revenue. Revenue for the three months ended September 30, 2014

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increased by $1,663,000, or 36%, compared to the three months ended September 30, 2013, and decreased by $184,000, or 1%, for the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 as discussed below.

The increase in revenue for the three months ended September 30, 2014 was due to higher consumables revenues of $6,042,000 compared to $3,986,000 for the same period of the prior year. This increase in consumables revenue was primarily attributable to an increase in purchases of our infectious disease assays. Pricing changes did not have an impact on revenue during the current quarter.

During the nine months ended September 30, 2013, revenue from former customer, Natural Molecular Testing Corporation, or NMTC, was $8,162,000. Excluding this former customer, our base business revenue grew 62% to $20,768,000 in the nine month period ended September 30, 2014 compared to $12,789,000 in the same period of 2013. Consumables revenue, from our base business, during the nine months ended September 30, 2014 increased by 75% over the prior year period. The increase in revenue from our base business was primarily attributable to an increase in purchases of our infectious disease assays. Pricing changes did not have an impact on revenue during the current period.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Cost of Revenue	$2,692	$4,138	$(1,446)	(35)%	$9,591	$12,373	$(2,782)	(22)%
Gross Profit	$3,608	$499	$3,109	623 %	$11,177	$8,579	$2,598	30 %

The decrease in cost of revenue of $1,446,000, or 35%, for the three months ended September 30, 2014, compared to the same period of the prior year, was primarily attributable to inventory reserve expense of $1,110,000, recorded in 2013, related to NMTC and a decrease in depreciation and amortization expense of $339,000. The $3,109,000 increase in gross profit for the three months ended September 30, 2014 was primarily due to increased sales volume in the current period and one-time charges related to NMTC in the prior year.

The decrease in cost of revenue of $2,782,000, or 22%, for the nine months ended September 30, 2014, compared to the same period of the prior year, was primarily attributable to inventory reserve expense of $1,115,000, recorded in 2013, related to NMTC, decreased overhead expenses, including headcount and temporary labor of $862,000, and a decrease in depreciation and amortization expense of $379,000. The $2,598,000 increase in gross profit for the nine months ended September 30, 2014 was primarily due to a decrease in product costs and one-time charges related to NMTC in the prior year.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Sales and Marketing	$3,159	$4,916	$(1,757)	(36)%	$9,516	$9,830	$(314)	(3)%

Sales and marketing expense decreased $1,757,000, or 36%, for the three months ended September 30, 2014, compared to the same period of the prior year, primarily driven by a one-time charge to bad debt expense of $2,472,000, recorded in 2013, related to amounts owed by NMTC, partially offset by increases in salaries and personnel related costs of $646,000, including stock-based compensation expense of $138,000.

Sales and marketing expense decreased $314,000, or 3%, for the nine months ended September 30, 2014, compared to the same period of the prior year, primarily driven by a one-time charge to bad debt expense of $2,702,000, recorded in 2013, related to amounts owed by NMTC and a decrease in consulting expenses of $261,000. These decreases were partially offset by increases in salaries and personnel related costs of $2,282,000, including stock-based compensation expense of $560,000, and increased travel expenses of $171,000 incurred in connection with our commitment to building our global commercial team.

	Three Months Ended	Nine Months Ended

	September 30,				September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
General and Administrative	$2,817	$2,476	$341	14 %	$8,760	$7,572	$1,188	16 %

General and administrative expense increased $341,000, or 14%, for the three months ended September 30, 2014, compared to the same period of the prior year, primarily driven by an increase in personnel related costs of $282,000, including stock-based compensation expense of $181,000, and an increase in audit and tax expense of $102,000 due to timing of work performed. The increases were partially offset by a decrease in consulting expenses of $279,000.

General and administrative expense increased $1,188,000, or 16%, for the nine months ended September 30, 2014, compared to the same period of the prior year, primarily driven by an increase in personnel related costs of $1,001,000, including stock-based

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compensation expense of $705,000, and an increase in audit and tax expense of $224,000 due to an increase in our operations. These increases were partially offset by decreases in consulting expenses of $404,000.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Research and Development	$7,904	$5,398	$2,506	46 %	$23,297	$15,786	$7,511	48 %

Research and development expense increased $2,506,000, or 46%, for the three months ended September 30, 2014, compared to the same period of the prior year, primarily due to increased ePlex™ instrument expenses of $1,854,000, and assay development expenses of $737,000. These increases were partially offset by a decrease in professional fees for software development of $244,000. Overall increases in research and development expenses were attributable to outside services costs and headcount to support the development of our ePlex™ system.

Research and development expense increased $7,511,000, or 48%, for the nine months ended September 30, 2014, compared to the same period of the prior year. The increase was primarily due to increased ePlex™ instrument expenses of $5,653,000, assay development expenses of $2,657,000, increased patent prosecution and other intellectual property related legal fees of $265,000, and increased clinical trial expenses of $222,000. These increases were partially offset by a decrease in professional fees for software development of $1,268,000. Overall increases in research and development were attributable to outside services costs and headcount to support the development of our ePlex™ system.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Other Income (Expense)	$(2)	$1,497	$(1,499)	(100)%	$154	$1,628	$(1,474)	(91)%

Other income (expense) represents non-operating income and expense, including, but not limited to, earnings on cash, cash equivalents, restricted cash, marketable securities, as well as interest expense related to debt, and capital leases.

The change in other income (expense) for the three months ended September 30, 2014, compared to the same period of the prior year, was due primarily to the sale of our preferred stock investment in Advanced Liquid Logic, Inc., or ALL, in connection with ALL's acquisition by Illumina, Inc., in the prior year, resulting in a $1,383,000 realized gain, recorded in the prior year, and an increase in amortization on premiums of marketable securities of $113,000, partially offset by an increase in interest income earned on investments of $14,000.

The change in other income (expense) for the nine months ended September 30, 2014, compared to the same period of the prior year, was due primarily to the sale of our preferred stock investment in ALL in connection with ALL's acquisition by Illumina, Inc., in the prior year, resulting in a $1,383,000 realized gain, recorded in the prior year, and an increase in amortization of premiums on marketable securities of $444,000, partially offset by an increase in interest income earned on investments of $369,000.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2014	2013	$ Change	% Change	2014	2013	$ Change	% Change
Income tax expense (benefit)	$(616)	$23	$(639)	(2,778)%	$(591)	$30	$(621)	(2,070)%

Due to our net losses, we have only recorded tax provisions associated with uncertain tax positions, interest on uncertain tax positions and minimum tax payments. The decrease in income tax expense for the three and nine months ended September 30, 2014 is due to a reduction in the unrecognized tax benefits associated with uncertain tax positions of $610,000, as a result of the expiration of applicable statute of limitations.

Liquidity and Capital Resources

To date, we have funded our operations primarily from the sale of our common stock, borrowings and cash from operations. We have incurred net losses from continuing operations each year and have not yet achieved profitability. As of September 30, 2014, we had $73,166,000 of working capital, including $79,248,000 in cash, cash equivalents, and marketable securities.

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

Nine months ended (in thousands):	September 30, 2014	2013
Net cash used in operating activities	$(22,232)	$(17,500)
Net cash provided by (used in) investing activities	11,644	(51,367)
Net cash provided by financing activities	523	80,891
Net increase (decrease) in cash and cash equivalents	$(10,065)	$12,024

Cash flows used in operating activities

Net cash used in operating activities increased $4,732,000 for the nine months ended September 30, 2014 compared to the same period of the prior year. The change was primarily due to an increase in net loss of $6,640,000 and a decrease in the provision for bad debt of $2,720,000, partially offset by a decrease in accounts receivable of $2,036,000, an increase in accrued compensation and stock-based compensation of $1,728,000 and $1,781,000, respectively, and a decrease in inventories of $425,000.

Cash flows provided by (used in) investing activities

Net cash provided by investing activities increased by $63,011,000 for the nine months ended September 30, 2014, compared to the same period of the prior year, primarily due to increases in net proceeds from maturities and sales of marketable securities of $38,697,000, and a decrease in purchases of marketable securities of $24,787,000.

Cash flows provided by financing activities

Net cash provided by financing activities decreased by $80,368,000 for the nine months ended September 30, 2014, compared to the same period of the prior year, primarily due to the public offering of our common stock in the prior year period and no such offering in 2014, a decrease in proceeds from borrowings of $166,000 and proceeds from the exercise of employee stock options of $163,000, offset by a decrease of costs incurred in conjunction with the public offering of $5,180,000 and a decrease in principal repayment of borrowings of $655,000.

We have prepared cash flow forecasts which indicate, based on our current cash resources available, that we will have sufficient resources to fund our business for at least the next 12 months. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, and expand our research and development, commercialization and manufacturing activities. Factors that could affect our capital requirements, in addition to those previously identified, include, but are not limited to:

- the level of revenues and the rate of our revenue growth;
- change in demand from our customers;
- the level of expenses required to expand our commercial (sales and marketing) activities;
- the level of research and development investment required to develop our ePlex™ system and related test menu and maintain our XT-8 system;
- our need to acquire or license complementary technologies;
- 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.

On August 19, 2013, we completed the public offering of 8,765,000 shares of our common stock at a price of $9.84 per share and raised approximately $80,672,000 in net proceeds.

If additional capital is required, we cannot be certain that it will be available when needed or that our actual cash requirements will not be greater than anticipated. 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 may be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

In September 2012, we entered into a term loan with Banc of California, consisting of the following two loans.

1) We increased the letter of credit provided to our landlord of our Carlsbad, California facility to $758,000 from the previous letter of credit of $500,000. The increase in the letter of credit was required by our landlord in connection with our lease of additional space at this facility. This letter of credit was secured with $758,000 of restricted cash at September 30, 2014.
2) We obtained a variable rate term loan from Banc of California in the amount of $836,000 with an initial interest rate of 3.75% that expired in July 2013. As of December 31, 2013, we had repaid all outstanding amounts under this loan.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our estimates on an ongoing basis, including those related to doubtful accounts, 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, 2013, and there have been no material changes to such policies or estimates during the nine months ended September 30, 2014.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements. We have provided a $758,000 standby letter of credit to our landlord as security for future rent in connection the lease of our Carlsbad, California facility, which is recorded as restricted cash on our unaudited condensed consolidated balance sheets.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risks during the quarter ended September 30, 2014.
Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of less than three months and marketable securities, which have maturities of greater than three months. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may in the future maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. We currently do not hedge interest rate exposure. Because of the short-term nature of our cash equivalents and investments, we do not believe that an increase in market rates would have a material negative impact on the value of our portfolio.

Interest Rate Risk
As of September 30, 2014, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

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. We currently have no material operations outside of the United States, which significantly diminishes the extent of any foreign currency exchange risk we currently face.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures
We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports we file under the Exchange Act is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.
As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer, with the participation of management, concluded that, as of September 30, 2014, our disclosure controls and procedures were effective.

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

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below and all of the other information set forth in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in evaluating our business and prospects. If any of the risks described below occurs, our business, financial condition or results of operations could be negatively affected. In that case, the market price of our common stock could decline.

We have marked with an asterisk (*) those risks described below that reflect new risks or substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2013.

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

We are designing our ePlex™ system to integrate automated nucleic acid extraction and amplification with our eSensor® technology to allow technicians to be able to place raw or minimally prepared patient samples directly into our test cartridges and obtain results with significantly reduced or no technician hands-on processing time. Our current plan for achieving positive cash flow and our future growth projections relies upon the successful development and commercialization of our ePlex™ system and its related test menu.

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. Although we have significant experience with our proprietary eSensor® electrochemical detection technology, we have not thus far developed a complete, sample-to-answer diagnostic instrument system. Successfully completing this complex project will require the effective convergence of our eSensor® technology with a number of additional unique technologies. We may not be successful in completing the development of all of the currently intended features and benefits of the system or effectively managing the complexities of the development program.

In addition, the development of our ePlex™ system involves multiple collaboration partners. For example, in July 2012 we entered into a Development Collaboration and License Agreement with Advanced Liquid Logic, Inc., or ALL, which was acquired by Illumina Inc. in July 2013. This agreement established a collaborative program to develop in-vitro diagnostic products incorporating ALL's proprietary electro-wetting technology in conjunction with electrochemical detection. While we have signed agreements with each of our collaboration partners, we cannot completely control the resources our collaboration partners dedicate to our ePlex™ development program, and their internal priorities may change over time. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct its collaborative activities successfully, in a timely or cost effective manner, or if we are otherwise unsuccessful in effectively managing the complexities of our ePlex™ program, the development or commercialization of our ePlex™ system could be delayed or terminated, or could cost significantly more than expected.

We believe we have made significant progress in the development of our ePlex™ system and continue to remain highly focused on developing a multiplex, sample-to-answer diagnostic solution of the highest quality for our customers. Based on the development milestones we have achieved and our ongoing assessment of development progress relative to our development plan, we currently expect to complete the development of our ePlex™ system by the end of 2014 and launch the system in Europe shortly thereafter. In addition, we expect to launch the ePlex™ system in the United States in the second half of 2015. However, our current estimates are based on a number of assumptions which could prove to be inaccurate or we may experience unanticipated technical or regulatory challenges or other delays. If we

are unsuccessful in completing development and commercializing our ePlex™ system within our expected time frame, or at all, our business and future prospects may be adversely affected.

We and our key suppliers may have difficulties scaling manufacturing operations for our anticipated future growth. To date, we have produced our products in limited quantities relative to the quantities necessary to achieve our desired revenue growth. In addition, developing the necessary manufacturing and quality procedures internally and in conjunction with our key suppliers for a significant number of newly developed, unique products is a complex process. We or our suppliers may not be prepared to produce sufficient quantities of, or may have difficulty maintaining consistency and quality among, our products. If we or our key suppliers encounter difficulties in scaling manufacturing operations as a result of, among other things, process transfer

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complexities, quality control and quality assurance issues, and availability of components and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results within the time frame we expect, or at all.

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. If our management is unable to effectively prepare for our expected future growth, our expenses may increase more than anticipated, our revenue could grow more slowly than expected, and we may not be able to achieve our commercialization goals. Our failure to effectively implement the necessary processes and procedures and otherwise prepare for our anticipated growth could have a material adverse effect on our future financial condition and prospects.

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

Our future success depends on the belief by our target customers and the medical community that our molecular diagnostic products are a reliable, medically-relevant, accurate and cost-effective replacement for other diagnostic testing methods. Medical offices and many hospitals outsource their diagnostic testing needs to national or regional reference laboratories. Our business success depends on our ability to convince these target laboratories and hospitals to perform these tests internally with our products if they have historically outsourced their testing needs or have historically used non-molecular methods to perform such testing, or to replace their current molecular testing platforms with our system and its related test offerings.

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

•the relative convenience, ease of use, accuracy, scalability, and time-to-result of our diagnostic products over competing products;

•the introduction of new technologies and competing products that may make our technologies and products a less attractive solution for our target customers;

•the breadth of our menu of available diagnostic tests relative to our competitors;

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

•the acceptance in the medical community and key opinion leaders of our molecular diagnostic technology and products;

•the extent and success of our marketing and sales efforts; and

•general economic conditions.

Professional societies, government agencies, practice management groups, private health/science foundations and organizations involved in healthcare issues may publish guidelines, recommendations or studies for the healthcare and patient communities. Recommendations of government agencies or these other organizations may relate to such matters as 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 quarterly revenue and operating results may vary significantly and we may experience constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand.*

Revenue from our infectious disease products fluctuates based upon the occurrence of related outbreaks and changes in testing recommendations. Influenza and other respiratory-related outbreaks are usually more concentrated in the first and fourth quarters of the year. New information or the introduction of advanced treatment options with respect to a particular disease may also affect related testing. Although certain infectious disease outbreaks tend to occur each year, the timing, severity and length of these incidents varies from one year to another and can vary across different

patient populations. In addition, we may not accurately predict changes to infectious disease testing recommendations affecting our products. As a result, we may not be able to accurately forecast sales from our infectious disease products.

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.

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

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

•companies developing and marketing multiplex molecular diagnostics systems, including: Luminex; Nanosphere, Inc.; bioMerieux, which recently acquired BioFire Diagnostics, Inc.; Qiagen NV; Abbott Molecular Diagnostics, a division of Abbott Laboratories; Hologic, Inc. and Cepheid;

•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; bioMérieux; 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. LDTs may not currently be subject to the same regulatory requirements, including those requiring clinical trials and FDA review and clearance or approval that may apply to our diagnostic products.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies, our competitors improve their current products and expand their menu of diagnostic tests, and as we expand our operations internationally. Many of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, and more extensive manufacturing and distribution capabilities. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers' and prospective customers' needs on a timely basis.

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

Assuming we receive the applicable regulatory approvals, we plan to offer our molecular diagnostic products in European and other international markets in the near future. We intend to utilize a direct sales and technical support team in certain key European countries, which we expect will be augmented by marketing partners and distributors in other strategic areas as we expand internationally. We have introduced our XT-8 system to key opinion leader sites in certain countries as we establish our technology and certain tests within these markets in preparation for the international launch of our ePlex™ instrument system. If we are unable to establish the infrastructure or recruit highly qualified personnel to support our direct sales and support organization, or if we are unsuccessful in developing awareness and acceptance of our products and technology internationally, our future financial performance would be adversely affected. Furthermore, any distributors we establish may not commit the necessary resources to market and sell our products to meet our expectations. If distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or if we are unable to locate distributors in particular geographic areas, our ability to realize revenue growth based on sales outside the United States would be harmed.

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

The regulatory clearance or approval process for certain products is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from commercializing our products. We are investing significantly in the research and development of our ePlex™ instrument and its related molecular diagnostic tests to expand our future product offerings. Our molecular diagnostic products may be classified as Class II or Class III medical devices which will require 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States. For international commercialization, the classification of, and the regulatory pre-market requirements for, our molecular diagnostic products vary from country to country. There are a number of potential risks associated with the regulatory review processes for our products in development. For example, regulatory authorities may require that we conduct additional studies that could impact the cost associated with product development and could potentially delay commercial launch

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of the product. In addition, we may be unsuccessful in obtaining regulatory clearance for all of our desired intended uses for our products or product approval or clearance within certain jurisdictions.

The regulatory environment is constantly evolving. For example, the FDA conducted a review of the pre-market clearance process in response to internal and external concerns regarding the 510(k) program and, in January 2011, announced 25 action items designed to make the process more rigorous and transparent. Some of these proposals, if enacted, could impose additional regulatory requirements for device manufacturers 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. More recently, in July 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act, or the FDASIA. Among other things, the FDASIA includes several reforms which are further intended to clarify and improve medical device regulation both pre- and post-marketing. One of these provisions obligates the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. After submitting this report, the FDA is expected to issue revised guidance to assist device manufacturers in making this determination. Until then, manufacturers may continue to adhere to the FDA's 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA's continuing scrutiny of these issues remains unclear. Similarly, the European Union, or EU, is proposing to update the European Directive 98/79/EC on in vitro diagnostic medical device, or IVD Directive (IVDD), that could impact the classification of our molecular diagnostic products and result in additional regulatory requirements, which could delay our ability to CE Mark our products. Delays in receipt of, or failure to obtain, clearances or approvals for future products, including our ePlex™ instrument and products that are currently in design or development, would result in delayed, or no, realization of revenues from such products and in substantial additional costs, which could decrease our profitability.

We must also comply with the applicable FDA and foreign regulatory agency post-market requirements. Any failure to maintain post-market compliance with FDA or foreign regulatory requirements could harm our business, operations, and/or financial condition.

We derive revenues from the sale of research use only, or RUO, tests, which are not intended for diagnostic purposes. Clinical laboratories are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and may validate the clinical diagnostic use of a laboratory developed test, or LDT, specifically for use in their laboratory using any labeled products. FDA has traditionally practiced enforcement discretion regarding the use of the LDTs for clinical diagnostic purposes. However, the FDA has recently promulgated draft guidance which outlines stringent regulatory requirements for CLIA labs in order to use LDTs for clinical diagnostic application. These proposed requirements, if implemented, may result in a significant reduction in the sale of our RUO products, which could reduce our revenues and adversely affect our operations and/or financial condition.

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

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

In addition, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after the earliest filing date for which a benefit is claimed. For this reason, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed or may in the future file patent applications covering our products or technology similar to ours. Under the "first to invent" rules applicable to patents filed before March 2013, any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark

Office, or PTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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. For example, two recent Supreme Court cases, Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al. and Mayo Collaborative Services v. Prometheus Laboratories, have introduced additional questions regarding the patentability

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of isolated naturally occurring genes and gene fragments, proteins, peptides, natural products, and related diagnostic and therapeutic methods which are likely to be resolved only through continued litigation. The overall impact of these decisions and others on the molecular diagnostics industry remains uncertain and our interpretation of the scope of these rulings on existing or future patents may be inaccurate.

There is a substantial amount of litigation involving patent and other intellectual property rights in the medical device, biotechnology and pharmaceutical industries generally. From time to time, we may become engaged in litigation with third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights.

If a third party claims that we or any of our customers or collaborators infringe 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 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 funds to the extent necessary to continue our operations.

If third-party payors do not reimburse our customers for the use of certain of our products or if reimbursement levels are set too low for us to sell our products at a profit, we may have difficulty selling such products.

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

•a covered benefit under its health plan;

•appropriate and medically necessary for the specific indication;

•cost effective; and

•neither experimental nor investigational.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors may also 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 or condition 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 highly multiplexed 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 and Medicaid Services, or CMS, which is responsible for implementing the Medicare program, establishes payment levels and coverage rules

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under Medicare. Private payors establish rates and coverage rules independently. We cannot guarantee that any of our tests are or will be covered by the CPT codes that we believe may be applied to them or that any of our tests or other products will be approved for coverage or reimbursement by Medicare, Medicaid or any third-party payor.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Increasingly, Medicare, Medicaid and other third-party payors are challenging the prices charged for medical services, including molecular diagnostic tests. In July 2013, CMS released certain proposals that re-examined payment amounts for tests reimbursed under the Medicare clinical laboratory fee schedule due to changes in technology. CMS also proposed to bundle the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting, replacing the current methodology to make separate payments for the test. These changes went into effect on January 1, 2014. In addition, payment methodologies may be subject to changes in healthcare legislation. In February 2012, President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation required CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn serves as the base for 2014 and subsequent years. Levels of reimbursement may continue to decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may harm the demand and reimbursement available for our products, which in turn, could harm our product 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.

The CPT codes published for 2014 did not include rates for all codes and reduced the reimbursement amounts for certain products, including some of our pharmacogenomics products. In addition, certain Medicare Administrative Contractors, or MACs, and private payors have issued draft coverage policies for pharmacogenomics testing that if implemented, would significantly restrict coverage for these tests. As a result, some of our pharmacogenomics customers have been negatively affected, which, in turn, has negatively affected the revenues we receive from these products.

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

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

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

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

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;

•possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;
•the potential obsolescence and/or inability of our suppliers to obtain required components;
•the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
•the inability to qualify alternate sources without impacting performance claims of our products;
•reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and
•increases in prices of raw materials and key components.

The manufacturing operations for our test cartridges use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly to repair or replace and could require substantial lead

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time to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facility or the facilities of any of our suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, or otherwise, would limit our ability to meet customer demand for our products and would have a material adverse effect on our business, financial condition and results of operations. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

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 approximately 135 owned and exclusively licensed patents and over 25 additional pending applications. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. A majority of our issued and exclusively licensed patents are scheduled to expire by 2021, with approximately one half of the patents expiring by 2018. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2034. However, not all of the pending or future patent applications owned by or licensed to us are guaranteed to mature into patents, and, moreover, issued patents owned by 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 licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we fail to comply with our material obligations under any of our patent license agreements, the licenses may be terminated and we could lose license rights that are important to our business. Furthermore, additional licenses we may need may not be available to us on commercially reasonable terms, or at all, which could adversely affect our results of operations and growth prospects.

In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the PTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011 the United States enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that have transitioned the United States from a “first-to-invent” system to a “first inventor to file” system and altered some of the processes for challenging issued patents. These changes may materially affect the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and patents of our collaborators and licensors.

The patent situation in the medical device and diagnostic fields outside the United States is even more uncertain. We have a number of foreign patents and pending 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

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proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us.

We 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. We have implemented procedures designed to ensure our compliance with relevant legal requirements. Nevertheless, if our marketing, sales or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition and results of operations.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or 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. Further, the 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. In February 2013, CMS released the final rule implementing the federal Physician Payments Sunshine Act, or the Sunshine Act. The law requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals. These new reporting requirements took effect on August 1, 2013. Failure to submit required information may result in significant civil monetary penalties. We expect compliance with the PPACA and Sunshine Act 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.

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

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

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

In addition, we have limited marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on attracting customers for our products and building brand loyalty. To successfully perform sales, marketing, distribution and customer support functions ourselves, we face a number of risks, including:

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

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

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

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

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

Federal and state governments in the United States are 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. Among other requirements, the PPACA imposes a 2.3% excise tax on sales of medical devices by manufacturers that is expected to cost the medical device industry up to $20 billion over the decade following its effectiveness. Taxable devices include any medical device defined in Section 201(h) of the FDCA and intended for use by humans, with limited exclusions for devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we began paying the tax in 2013. Complying with PPACA may significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

In August 2011, President Obama signed into law the Budget Control Act of 2011, which among other things, created automatic reductions to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. In January 2013, the American Taxpayer Relief Act of 2012, or the ATRA, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. In March 2013, President Obama signed an executive order implementing sequestration, and in April 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could

limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. We obtained FDA clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We initially offered our XT-8 system and our Warfarin Sensitivity Test in July 2008, our Cystic Fibrosis Genotyping Test in July 2009, our Thrombophilia Risk Test in April 2010, and our Respiratory Viral Panel in September 2012. Our net losses were approximately $33.6 million and $22.1 million for the years ended December 31, 2013 and 2012, respectively. As of September 30, 2014, we had an accumulated deficit of $253.9 million. We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing operations, primarily related to our commercial organization (sales and

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marketing), research and development and regulatory activities, maintaining our existing intellectual property portfolio, obtaining additional intellectual property rights and investing in corporate infrastructure. We cannot provide any assurance that we will achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our limited commercialization history and the rapidly evolving nature of our target market, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

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

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

In addition, our product development and marketing efforts could be delayed or curtailed if we are unable to attract, train and retain highly skilled technical employees and scientific advisors. To expand our research, product development and commercial 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 and our suppliers, contract manufacturers and customers are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these regulations.

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

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

substantial monetary penalties and criminal prosecution.

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

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

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

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

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

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

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

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

Although we have recently remediated a material weakness in our internal control over financial reporting, if we are unable to maintain the effectiveness of our internal controls, our financial results may not be accurately reported. Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2011 reported a material weakness in our internal control over financial reporting related to the supervision and review of our financial closing and reporting process, as described in our Annual Report on Form 10-K for the year ended December 31, 2011. During 2012 and 2013, we devoted significant time and resources to the remediation of the material weakness which included, but was not limited to:

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•evaluating our finance department's management and staff qualifications, which resulted in us making certain personnel changes;
•redesigning and implementing structured and formalized internal control procedures;
•implementing new control procedures over the utilization of external resources; and
•developing and initiating a plan for the deployment of additional software systems to assist in automating and controlling certain financial processes.

Although further and ongoing efforts will continue in 2014 and beyond to enhance our internal control over financial reporting, we believe that our remediation efforts now provide the foundation for compliance with the Committee of Sponsoring Organizations (1992 framework) (COSO) of the Treadway Commission framework. As a result, our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012 and 2013 no longer reported this material weakness or any other material weakness over financial reporting, and the audit report of our independent registered public accounting firm no longer expressed an adverse opinion on the effectiveness of our internal control over financial reporting as of December 31, 2013.

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

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 may be outside of our control. These factors include, but are not limited to:
•the time and resources required to develop, and conduct clinical studies and obtain regulatory clearances for, additional diagnostic tests;
•the expenses we incur for research and development required to maintain and improve our technology, including developing our ePlex™ system;
•the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
•the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution expenses;
•the expenses we incur in licensing technologies from third parties to expand the menu of diagnostics tests we plan to offer;
•our sales strategy and whether the revenues from sales of our test cartridges or XT-8 system will be sufficient to offset our expenses;
•the costs to attract and retain personnel with the skills required for effective operations; and
•the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our XT-8 system and its related test menu, as well our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with our ePlex™ system. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our business and financial condition.

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

As a public company listed in the United States, we incur significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC, the Public Company Accounting Oversight Board (PCAOB), and The NASDAQ Global Market, may

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increase our legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If we nevertheless fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

Global economic conditions may remain challenging and uncertain for the foreseeable future. These conditions not only limit our access to capital but also make it extremely difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign businesses and consumers to slow spending on our products and services, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government's allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers, increase our allowance for doubtful accounts, and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we may not continue to experience the same loss rates that we have in the past. 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.

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, adjustments to our depreciation assumptions, 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. For example, during the year ended December 31, 2013, we recorded an impairment charge of $1.6 million related to previously capitalized payments made under the terms of a license agreement, which we terminated in December 2013. 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.

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

The majority of our XT-8 systems are provided to customers via "reagent rental" agreements, under which customers are afforded the right to use the XT-8 system in return for a commitment to purchase minimum quantities of reagents and test cartridges over a period of time. Accordingly, we must either incur the expense of manufacturing XT-8 systems well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our XT-8 systems. The amount of capital required to provide these systems to customers depends on the number of systems placed. Our ability to generate capital to cover these costs depends on

the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we cannot sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected.

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

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

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

As of December 31, 2013, we had net operating loss, or NOL, carryforwards available of approximately $89.9 million million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2033. Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, generally imposes an annual limitation on the amount of NOL carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in stock ownership. We have determined that we have experienced multiple ownership changes under Section 382 of the Code. Our ability to use the current NOL carryforwards may also be limited by the issuance of common stock in the future. To the extent our use of NOL carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use NOL carryforwards. We have recorded a full valuation allowance against our net deferred tax assets.

We also had non-U.S. NOL carryforwards as of December 31, 2013. As a result of the liquidation of Osmetech plc in the fourth quarter of 2013, our expectation is that the non-U.S. NOL carryforwards will not be utilized and, therefore, we have not accounted for them as a deferred tax asset.

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.

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

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

•allow the authorized number of directors to be changed only by resolution of our Board of Directors;

•provide that our stockholders may remove our directors only for cause;

•establish a classified board of directors, such that not all members of the Board of Directors may be elected at one time;

•authorize our Board of Directors to issue without stockholder approval up to 100,000,000 shares of common stock, that, if issued, would dilute our stock ownership and could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
•authorize our Board of Directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
•require that stockholder actions must be effected at a duly called stockholder meeting or by unanimous written consent;
•establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings;

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•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.

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

None.

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.

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: October 30, 2014	By:	/s/ Hany Massarany Hany Massarany President and Chief Executive Officer (Principal Executive Officer)
Date: October 30, 2014	By:	/s/ Scott Mendel Scott Mendel Chief Financial Officer (Principal Financial and Accounting Officer)

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EXHBIT INDEX

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

Exhibit	Description
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 SEC on March 19, 2010).
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.