GenMark Diagnostics, Inc.
Form 10-Q
November 14, 2011
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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, 2011

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

For the transition period from to

Commission File Number: 001-34753

GenMark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

The number of outstanding shares of the registrant s common stock on November 5, 2011 was 20,477,820.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

(Unaudited)

	As of September 30, 2011	As of December 31, 2010
Current assets		
Cash and cash equivalents	$ 31,001	$ 18,329
Short-term investments	5,000	
Accounts receivable, net of allowance of $111 and $39 at September 30, 2011 and December 31, 2010, respectively	724	678
Inventories	1,963	897
Other current assets	428	2,193
Total current assets	39,116	22,097
Property and equipment, net	3,122	2,702
Intangible assets, net	1,382	1,460
Other long-term assets	80	55
Total assets	$ 43,700	$ 26,314
Current liabilities		
Accounts payable	$ 1,496	$ 823
Accrued compensation	1,219	1,172
Current portion of loan payable	1,000	
Other current liabilities	2,705	1,945
Total current liabilities	6,420	3,940
Long-term liabilities		
Loan payable	833	
Other non-current liabilities	630	1,307
Total liabilities	$ 7,883	$ 5,247
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued		
Common stock, $0.0001 par value; 100,000 authorized; 20,478 and 11,728 issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	2	1
Additional paid-in capital	199,300	166,009
Accumulated deficit	(163,027)	(144,493)
Accumulated other comprehensive loss	(458)	(450)
Total stockholders equity	35,817	21,067

Total liabilities and stockholders equity	$ 43,700	$ 26,314

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine months Ended September 30,	
	2011	2010	2011	2010
Product Revenue	$ 1,206	$ 656	$ 2,765	$ 1,563
License and other revenue	110	28	210	196
Total revenue	1,316	684	2,975	1,759
Cost of sales	1,785	1,123	4,580	2,372
Gross loss	(469)	(439)	(1,605)	(613)
Operating expenses				
Sales and marketing	1,328	1,173	3,767	3,567
General and administrative	2,405	1,603	6,338	5,798
Research and development	1,903	1,709	6,759	4,935
Total operating expenses	5,636	4,485	16,864	14,300
Loss from operations	(6,105)	(4,924)	(18,469)	(14,913)
Other income				
Other income (expense)	(180)		(50)	(1)
Interest income (expense)	(29)	7	6	16
Total other income (expense)	(209)	7	(44)	15
Loss before income taxes	(6,314)	(4,917)	(18,513)	(14,898)
Provision for income taxes	1		(21)	(5)
Net loss	$ (6,313)	$ (4,917)	$ (18,534)	$ (14,903)
Net loss per share, basic and diluted	$ (0.31)	$ (0.42)	$ (1.20)	$ (1.63)
Weighted average number of shares outstanding	20,043	11,724	15,393	9,142
Condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2011 and 2010				
Net loss	$ (6,313)	$ (4,917)	$ (18,534)	$ (14,903)
Foreign currency translation adjustment	56		(8)	(35)
Comprehensive loss	$ (6,257)	$ (4,917)	$ (18,542)	$ (14,938)

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine months Ended September 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (18,534)	$ (14,903)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	948	725
Share-based compensation	1,639	1,119
Inventory write-down	428	984
Changes in operating assets and liabilities:		
Trade accounts receivable	(46)	(363)
Inventories	(1,448)	(1,510)
Other current assets	1,741	183
Accounts payable	510	(446)
Accrued compensation	22	517
Accrued and other liabilities	731	104
Net cash used in operating activities	(14,009)	(13,590)
Investing activities:		
Payments for intellectual property licenses	(728)	
Purchases of property and equipment	(1,172)	(1,398)
Purchase of short-term investments	(5,000)	
Net cash used in investing activities	(6,900)	(1,398)
Financing activities:		
Proceeds from issuance of ordinary shares and common stock	34,532	27,600
Costs incurred in conjunction with public offering	(2,790)	(4,909)
Proceeds from borrowings	2,000	
Principal repayment of borrowings	(167)	
Proceeds from stock option exercises		5
Net cash provided by financing activities	33,575	22,696
Effect of foreign exchange rate changes	6	(47)
Net increase in cash and cash equivalents	12,672	7,661
Cash and cash equivalents at beginning of period	18,329	16,483
Cash and cash equivalents at end of period	$ 31,001	$ 24,144

See accompanying notes to unaudited condensed consolidated financial statements.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

(unaudited)

1. Organization and basis of presentation

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

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

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

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

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

(iv) the accumulated deficit represents the aggregate of the accumulated deficit of Osmetech and the Company.

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

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

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $163.0 million at September 30, 2011. Cash and cash equivalents and short-term investments at September 30, 2011 were $36.0 million.

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

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for audited financial statements. In the opinion of management, all adjustments, which include only normal recurring adjustments considered necessary for a fair presentation, have been included. Operating results for the nine months ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ending December 31, 2011. The information presented in the condensed consolidated financial statements and related footnotes at September 30, 2011, and for the three and nine months ended September 30, 2011 and 2010, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2010 have been derived from our audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in our annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 2011.

Segment Information

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

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

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Recent Accounting Pronouncements

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

Fair Value of Financial Instruments

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

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

The following table presents the Company s hierarchy for assets measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 (in thousands):

	September 30, 2011			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents	$ 23,225	$	$	$ 23,225
Certificates of deposit		8,000		8,000

	December 31, 2010			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents	$ 16,707	$	$	$ 16,707

Cash and cash equivalents and short-term investments

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

Concentration of Risk

The Company had sales to one customer representing approximately 14% of total revenues for the nine months ended September 30, 2011. Also, the Company s XT-8 system is manufactured by a single source supplier that specializes in contract design and manufacturing of electronic and electromechanical devices for medical use.

Product Shipment Costs

Product shipment costs are included in sales and marketing expense in the accompanying Condensed Consolidated Statements of Operations. Shipping and handling costs were $134,000 and $142,000 for the nine months ended September 30, 2011 and 2010, respectively.

Product Warranties

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

Impairment of Long-Lived Assets

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

Income Taxes

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

Corporate Reorganization

During the quarter ended June 30, 2011, the Company underwent a corporate reorganization (the Reorganization) intended to simplify its U.S. entity structure. As part of the Reorganization, Osmetech Technologies, Inc. merged into Clinical Micro Sensors, Inc. (CMS), with CMS surviving. Additionally, Osmetech plc converted to a U.K. limited company for U.K. legal and tax purposes, and made an entity classification election to be treated as an entity disregarded from GenMark Diagnostics, Inc. for U.S. federal income tax purposes. It is anticipated that the Reorganization will not trigger any material U.S. federal or U.K. income tax expense. Additionally, it is anticipated that the post-Reorganization structure will allow GenMark Diagnostics, Inc. to elect to file a consolidated U.S. federal income tax return with its remaining U.S. subsidiaries, CMS and Osmetech, Inc.

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2. Share-Based Compensation

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

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

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

Options are generally exercisable for a period up to 10 years after grant and are forfeited if the employee leaves the Company before the options vest. As of September 30, 2011, 169,428 shares remained available for future grant of awards under the Plan. Restricted stock grants reduce the amount of stock options available for grant under the 2010 Plan and are excluded from the table below.

The following table summarizes stock option activity during the nine months ended September 30, 2011:

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2010	1,107,920	$ 6.40
Granted	695,000	$ 4.33
Exercised		
Cancelled	(249,035)	$ 6.63
Outstanding at September 30, 2011	1,553,885	$ 5.42
Exercisable at September 30, 2011	534,046	$ 6.49

As of September 30, 2011, there were 1,469,624 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.48 years, and an aggregate intrinsic value of $1,020,823.

Valuation of Share-Based Awards The Black-Scholes option pricing model was used for estimating the grant date fair value of stock options granted during the nine months ended September 30, 2011 with the following assumptions:

Expected volatility (%)	70.00
Expected life (years)	6.08
Risk free rate (%)	2.50

Expected dividend yield (%)	0.00
Estimated forfeitures (%)	5.00

During the nine months ended September 30, 2011, the Company granted 425,169 shares of restricted stock to employees and 10,000 shares of restricted stock to an outside consultant. The restricted stock granted to employees generally vests over a four year period except for 4,000 shares of restricted stock issued to one employee as part of a separation agreement that vested on May 31, 2011 and 222,926 shares issued to senior management employees that vested May 5, 2011. The restricted stock granted to the outside consultant vested on March 31, 2011 commensurate with the period of service rendered to the Company.

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3. Net Loss per Common Share

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

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

	September 30,	
	2011	2010
Weighted average stock options	1,554	1,121
Warrants	88	88
Restricted Stock unvested, issued and held in escrow	427	
Restricted Stock vested, not issued or outstanding		4
Total	2,069	1,213

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

4. Property and Equipment, net

Property and equipment was comprised of the following as of September 30, 2011 and December 31, 2010 *(in thousands)*:

	September 30, 2011	December 31, 2010
Property and equipment at cost:		
Plant and machinery	$ 2,539	$ 2,452
Instruments	3,959	2,822
Office equipment	1,574	1,542
Leasehold improvements	537	596
Total property and equipment at cost	8,609	7,412
Less accumulated depreciation	(5,487)	(4,710)
Net property and equipment	$ 3,122	$ 2,702

Depreciation expense was $869,000 and $672,000 for the nine months ended September 30, 2011 and 2010, respectively.

5. Loan payable

In March 2010, the Company entered into a loan and security agreement with Square 1 Bank, pursuant to obtaining a credit facility consisting of a revolving line of credit in the amount of up to $2 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of September 30, 2011) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

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

As of September 30, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had a balance of $1.8 million used to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility on the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% were due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that were then outstanding are payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

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

6. 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, 2011, the Company has recorded a full valuation allowance against all of its net deferred tax assets due to the uncertainty surrounding the Company s ability to utilize these assets in the future. Provision for income tax was $22,000 and $5,000 for the nine months ended September 30, 2011 and 2010, respectively. Due to the Company s losses it only records tax provision or benefit related to minimum tax payments or refunds and interest and penalties related to its uncertain tax positions.

The total amount of unrecognized tax benefits was $382,000 as of September 30, 2011 which would impact the effective tax rate if recognized. The gross liability for income taxes related to unrecognized tax benefits is included in other long-term liabilities in the Company s condensed consolidated balance sheets.

The total balance of accrued interest related to uncertain tax positions was $116,000 as of September 30, 2011. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. The Company does not expect its unrecognized tax benefits to change significantly over the next twelve months.

The Company is subject to taxation in the U.S., the U.K. based on its legacy operations, and in various state jurisdictions. As of September 30, 2011 the Company s tax years after 2007 are subject to examination by the U.K. tax authorities. Except for net operating losses generated in prior years carrying forward to the current year, as of September 30, 2011, the Company is no longer subject to U.S. federal, state, local or foreign examinations by tax authorities for years before 2006.

7. Common stock offering

The Company issued 8,125,440 shares of common stock on June 22, 2011 at a price of $4.25 per share, which included a public offering of 7,065,600 shares and 1,059,840 purchased by the underwriter in accordance with the over-allotment provisions of their agreement. The Company raised approximately $31.7 million in net proceeds after deducting underwriting discounts and commissions of $2.2 million and other offering expenses of $0.6 million.

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8. Unrecorded licensing agreement and reclassifications

Subsequent to the issuance of the 2010 audited financial statements, the Company concluded that a contract for the purchase of certain intellectual property rights should have been recorded as both an asset and a liability in the financial statements for the periods ended December 31, 2010 and March 31, 2011. The contract was properly recorded in the financial statements for the period ended June 30, 2011. The Company has recorded this contract which results in an increase of $1,389,000 to intangible assets for the year ended December 31, 2010 and for the period ended March 31, 2011, respectively. The current and long-term portion of the liability for the contract was $695,000 and $694,000 and $1,043,000 and $346,000 respectively as of December 31, 2010 and March 31, 2011. As of September 30, 2011, the current and long-term portion of the obligation for the contract was $726,000 and $0, respectively.

Subsequent to the issuance of the 2010 audited financial statements, the Company further concluded that certain expenses were classified incorrectly in its Consolidated Statements of Operations for the past periods presented herein, with no net impact to operating loss, net loss, statements of cash flows or balance sheets. The Company has corrected these immaterial misstatements. These corrections result in reductions to cost of sales of $98,000 and $279,000 in the quarter and nine month period ending September 30, 2010 and corresponding increases to revenues and sales and marketing, general and administrative and research and development expenses.

Additionally, based on a loan amendment dated March 2011, the Company should have reclassified $667,000 of its loan payable to current portion of long-term debt at March 31, 2011. The Company corrected this presentation in subsequent filings.

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The following tables reconcile the As Reported financial statements with the As Corrected financial statements.

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

(unaudited)

	As Reported December 31, 2010	Adjustment	As Corrected December 31, 2010
Current assets			
Cash and cash equivalents	$ 18,329		$ 18,329
Accounts receivable, net of allowance of $39 at December 31, 2010	678		678
Inventories	897		897
Other current assets	2,193		2,193
Total current assets	22,097		22,097
Property and equipment, net	2,702		2,702
Intangible assets, net	71	1,389	1,460
Other long-term assets	55		55
Total assets	$ 24,925	$ 1,389	$ 26,314
Current liabilities			
Accounts payable	$ 823		$ 823
Accrued compensation	1,172		1,172
Other current liabilities	1,250	695	1,945
Total current liabilities	3,245	695	3,940
Long-term liabilities			
Loan payable			
Other non-current liabilities	613	694	1,307
Total liabilities	$ 3,858	$ 1,389	$ 5,247
Stockholders equity			
Preferred stock, $0.0001 par value; 5,000 authorized, none issued			
Common stock, $0.0001 par value; 100,000 authorized; 11,728 issued and outstanding as of December 31, 2010	1		1
Additional paid-in capital	166,009		166,009
Accumulated deficit	(144,493)		(144,493)
Accumulated other comprehensive loss	(450)		(450)
Total stockholders equity	21,067		21,067
Total liabilities and stockholders equity	$ 24,925	$ 1,389	$ 26,314

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	As Reported Three Months Ended September 30, 2010	Adjustments Three Months Ended September 30, 2010	As Corrected Three Months Ended September 30, 2010
Product Revenue	$ 653	$ 3	$ 656
License and other revenue	14	14	28
Total revenue	667	17	684
Cost of sales	1,221	(98)	1,123
Gross loss	(554)	(115)	(439)
Operating expenses			
Sales and marketing	1,109	64	1,173
General and administrative	1,592	11	1,603
Research and development	1,669	40	1,709
Total operating expenses	4,370	115	4,485
Loss from operations	(4,924)		(4,924)
Other income			
Other income (expense)			
Interest income (expense)	7		7
Total other income	7		7
Loss before income taxes	(4,917)		(4,917)
Provision for income taxes			
Net loss	$ (4,917)	$	$ (4,917)
Net loss per share, basic and diluted	$ (0.42)		$ (0.42)
Weighted average number of shares outstanding	11,724		11,724
Condensed consolidated statements of comprehensive loss for the three months ended September 30, 2010			
Net loss	$ (4,917)		$ (4,917)
Foreign currency translation adjustment			
Comprehensive loss	$ (4,917)		$ (4,917)

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	As Reported Nine months ended September 30, 2010	Adjustments Nine months ended September 30, 2010	As Corrected Nine months ended September 30, 2010
Product Revenue	$ 1,575	$ (12)	$ 1,563
License and other revenue	142	54	196
Total revenue	1,717	42	1,759
Cost of sales	2,651	(279)	2,372
Gross loss	(934)	(321)	(613)
Operating expenses			
Sales and marketing	3,371	196	3,567
General and administrative	5,761	37	5,798
Research and development	4,847	88	4,935
Total operating expenses	13,979	321	14,300
Loss from operations	(14,913)		(14,913)
Other income			
Other income (expense)	(1)		(1)
Interest income (expense)	16		16
Total other income	15		15
Loss before income taxes	(14,898)		(14,898)
Provision for income taxes	(5)		(5)
Net loss	$ (14,903)	$	$ (14,903)
Net loss per share, basic and diluted	$ (1.63)	$	$ (1.63)
Weighted average number of shares outstanding	9,142		9,142
Condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2010			
Net loss	$ (14,903)	$	$ (14,903)
Foreign currency translation adjustment	(35)		(35)
Comprehensive loss	$ (14,938)		$ (14,938)

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

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements and notes included in Item 1 of this Quarterly Report for the nine months ended September 30, 2011, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2010, included in our Annual Report on Form 10-K dated March 11, 2011. This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as we expect, anticipate, target, project, believe, goals, estimate, potential, may, will, expect, might, could, intend, variations of these terms or the negative of those terms and similar expressions are intended to ide these forward-looking statements. Readers are cautioned that these forward-looking statements are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2010 and our risk factors described under the heading Risk Factors in Item 1A of Part II of our Quarterly Report for the quarter ended June 30, 2011. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

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

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the FDA and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within 30 minutes of receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports between one and three analyzers. Each analyzer holds up to eight independent test cartridges, resulting in the XT-8 system supporting up to 24 test cartridges, each of which can be run independently, resulting in a convenient and flexible workflow for our target customers, which are hospitals and reference laboratories. As of September 30, 2011, we had an installed base of 141 analyzers, or placements, with our customers.

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

We are also developing our next-generation platform, the NexGen system. We are designing the NexGen system to integrate automated nucleic acid extraction and amplification with our eSensor detection technology to enable technicians using the NexGen system to be able to place a raw or a minimally prepared patient sample into our test cartridge and obtain results without any additional steps. This sample-to-answer capability is enabled by the robust nature of our eSensor detection

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technology, which is not impaired by sample impurities that we believe hinder competing technologies. We are designing our NexGen system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories.

Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the nine months ended September 30, 2011 and 2010 were approximately $18.5 million and $14.9 million, respectively. As of September 30, 2011, we had an accumulated deficit of $163.0 million. Our operations to date have been funded principally through sales of capital stock, borrowings and revenues. We expect to incur increasing expenses over the next several years, principally to develop additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Results of Operations Three months ended September 30, 2011 compared to the three months ended September 30, 2010 *(in thousands)*

Revenue

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ 1,316	$ 684	$ 632	92%

The increase in revenue for the three month period ended September 30, 2011 as compared to the three month period ended September 30, 2010 was due to higher reagent revenues of $550,000 driven by the increase in the number of our installed base of systems as well as an expanded menu of tests available for sale, including products at higher price points than legacy tests, and higher licensing revenues of $87,000 for the period.

Cost of Sales and Gross Loss

	September 30, 2011	2010	$ Change	% Change
Cost of Sales-three months ended	$ 1,785	$ 1,123	$ 662	59%
Gross Loss-three months ended	$ 469	$ 439	$ 30	7%

The increase in cost of sales for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to higher cost of goods sold expense of $366,000 directly related to the increase in reagent sales and an inventory charge of $421,000 recorded during the quarter. The inventory charge reflects the write-off of several assay production lots that did not meet the Company s quality standards and other manufacturing inefficiencies arising from the Company s transfer of manufacturing operations from Pasadena to Carlsbad during the second quarter of 2011. The increase in gross loss resulted primarily from costs associated with our expanded product offerings which will be reduced as a percentage of sales as our sales volume increases.

Operating Expenses

Sales and Marketing

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ 1,328	$ 1,173	$ 155	13%

The increase in sales and marketing expense was primarily driven by an increase in sales commissions due to the buildout of our commercial team as well as increased revenue for the three months ended September 30, 2011 compared to the three months ended September 30, 2010.

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General and Administrative

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ 2,405	$ 1,603	$ 802	50%

General and administrative expense increased for the three months ended September 30, 2011 due to increased outside service and consulting fees $393,000, an increase in personnel costs of $228,000, and additional audit and compliance-related consulting costs of $174,000 as compared to the three months ended September 30, 2010.

Research and Development

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ 1,903	$ 1,709	$ 194	11%

The increase in research and development expense for the three months ended September 30, 2011 was due primarily to increased clinical trial costs and spending for new product development, specifically the Company s Hepatitis C Virus genotyping (HCVg) and Respiratory Viral Panel tests.

Other Income (Expense), Net

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ (209)	$ 7	$ (216)	3086%

Other income (expense) represent non-operating revenue and expenses, earnings on cash and cash equivalents, interest expense related to a loan payable and foreign currency gains or losses. The increase in other (expense) for the three months ended September 30, 2011 as compared to the same period in 2010 was due primarily to a note payment received in a prior period that must be returned and interest expense related to the loan payable of $32,000.

Provision for Income Taxes

	September 30, 2011	2010	$ Change	% Change
Three months ended	$ (1)	$	$ (1)	100%

Due to the Company s losses it has only recorded tax provisions or benefits related to interest on uncertain tax positions, minimum tax payments and refunds.

Results of Operations Nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 *(in thousands)*

Revenue

	September 30, 2011	2010	$ Change	% Change
Nine months ended	$ 2,975	$ 1,759	$ 1,216	69%

The increase in revenue for the nine month period ended September 30, 2011 as compared to the nine month period ended September 30, 2010 was due to higher reagent sales of $1.2 million due to the increase in its number of our installed base of systems as well as an expanded menu of

tests available for sale, including products at higher price points than legacy tests.

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Cost of Sales and Gross Loss

	September 30,			
	2011	2010	$ Change	% Change
Cost of Sales-nine months ended	$ 4,580	$ 2,372	$ 2,208	93%
Gross Loss-nine months ended	$ 1,605	$ 613	$ 992	162%

The increase in cost of sales for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was due to higher cost of goods sold expense of $890,000 directly related to the increase in reagent sales, increased costs related to warranties of $116,000, higher depreciation of rental systems due to increased placements of $250,000, and an inventory write down of $421,000 recorded during the quarter. The inventory charge reflects the write-off of several assay production lots that did not meet the Company s quality standards and other manufacturing inefficiencies arising from the Company s transfer of manufacturing operations from Pasadena to Carlsbad during the second quarter of 2011. Additional costs incurred in relocating our manufacturing facilities from Pasadena to our Carlsbad location in 2011 included higher temporary labor costs of $230,000. The increase in gross loss resulted primarily from costs associated with our expanded product offerings which will be reduced as a percentage of sales as our sales volume increases and the one-time expense of relocating our manufacturing facility which was completed in June 2011.

Operating Expenses

Sales and Marketing

	September 30,			
	2011	2010	$ Change	% Change
Nine months ended	$ 3,767	$ 3,567	$ 200	6%

The increase in expense was primarily driven by increased commissions related to the buildout of our commercial team as well as higher revenues and sample costs for prospective customers offset by lower consulting and website development costs for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010.

General and Administrative

	September 30,			
	2011	2010	$ Change	% Change
Nine months ended	$ 6,338	$ 5,798	$ 540	9%

General and administrative expense increased for the nine months ended September 30, 2011 as compared to the nine months ended September 30, 2010 due to increases in consulting, outside services and professional services of $1,790,000, offset by lower personnel-related costs of $646,000, reduced expenses related to relocating our UK operations of $384,000, and lower exit costs related to our Pasadena facility of $202,000.

Research and Development

	September 30,			
	2011	2010	$ Change	% Change
Nine months ended	$ 6,759	$ 4,935	$ 1,824	37%

The increase in research and development expense for the nine months ended September 30, 2011 was due to higher clinical trial costs, including materials and consulting expenses of $1,769,000 related to RVP clinical trial, development of our HCVg assay, FDA certification of our new Carlsbad manufacturing facility and increased personnel costs of $613,000 that were offset by reductions in spending for lab supplies of $447,000 and outside services of $205,000 as compared to the same period in 2010.

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Other Income (Expense), Net

	September 30, 2011	2010	$ Change	% Change
Nine months ended	$ (44)	$ 15	$ (59)	(393)%

Other income (expense) represent non-operating income and expenses, earnings on cash and cash equivalents, interest expense on our loan payable and foreign currency gains or losses. The increase in other income (expense) for the nine months ended September 30, 2011 as compared to the same period in 2010 was due primarily to interest expense incurred on the term loan. There was no loan payable balance in 2010.

Provision for Income Taxes

	September 30, 2011	2010	$ Change	% Change
Nine months ended	$ 21	$ 5	$ 16	320%

Due to the Company s losses it has only recorded tax provisions or benefits related to interest on uncertain tax positions, minimum tax payments and refunds.

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock, borrowings and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At September 30, 2011, we had $32.7 million of working capital, including $36.0 million in cash and cash equivalents and short term investments.

Cash Flows

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

	September 30, 2011	2010
Nine months ended:		
Cash used by operating activities	$ (14,009)	$ (13,590)
Cash used by investing activities	(6,900)	(1,398)
Cash provided by financing activities	33,575	22,696
Effect of foreign exchange rate changes	6	(47)
Increase in cash and cash equivalents	$ 12,672	$ 7,661

Cash flows used by operating activities

Net cash used in operating activities increased $0.4 million to $14.0 million for the nine months ended September 30, 2011 compared to $13.6 million for the nine months ended September 30, 2010. The increased use of cash was due primarily to an increased net loss for the nine months ended September 30, 2011 and use of cash to increase inventory balances, accounts payable and accrued liabilities offset by the collection of a $1.6 million therapeutic tax credit in 2011.

Cash flows used by investing activities

Net cash used in investing activities increased $5.5 million to $6.9 million for the nine months ended September 30, 2011 compared to $1.4 million for the nine months ended September 30, 2010 due to purchasing a short-term investment for $5.0 million and a payment made for

intellectual property licensing in 2011.

Cash flows provided by financing activities

Net cash provided by financing activities increased by $10.9 million for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010. Cash provided in 2011 resulted from net proceeds of our secondary public offering and a $2.0 million term loan in 2011. Cash provided in 2010 resulted substantially from the net proceeds of our initial public offering.

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The Company issued 8,125,440 shares of common stock on June 22, 2011 at a price of $4.25 per share. We raised approximately $31.7 million in net proceeds after deducting underwriting discounts and commissions of $2.2 million and other offering expenses of $0.6 million.

In March 2010, we entered into a loan and security agreement with Square 1 Bank, pursuant to which we obtained a credit facility consisting of a revolving line of credit in the amount of up to $2 million and an equipment term loan in the amount of up to $2 million. Based upon certain financial covenants, interest on the revolving line of credit will be either (i) the greater of (a) the bank s prime rate (3.25% as of September 30, 2011) plus 2.75%, or (b) 6%; or (ii) the greater of (a) the bank s prime rate plus 3.75%, or (b) 7%. In addition, based upon certain financial covenants, interest on the equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. The revolving line matures in July 2011 and the term loan matures in July 2013. In March 2011, the loan and security agreement was amended, whereby the line of credit availability was increased to $3 million and the maturity was extended to July 2012. The term loan was modified to allow invoices up to 360 days to qualify to be submitted for credit extension. There were no other changes to these two loans.

In March 2011, an additional loan was made available under the amended loan and security agreement for up to $1 million to finance equipment purchases. Based upon certain financial covenants, interest on this equipment term loan will be either (i) the greater of (a) the bank s prime rate plus 3.25%, or (b) 6.50%; or (ii) the greater of (a) the bank s prime rate plus 4.25%, or (b) 7.50%. This term loan matures March 2014.

As of September 30, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had a balance of $1.8 million used to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility on the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% were due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that were then outstanding are payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

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

The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available, the availability of unutilized credit facilities, and our ability to access the equity markets, that we will have sufficient resources to fund our business for at least the next 12 months. We expect capital outlays and operating expenditures to increase over the next several years as we grow our customer base and revenues, expand our research and development, commercialization and manufacturing activities. The amount of additional capital we may need to raise in the future depends on many factors, including:

- the level of revenues and the rate of revenue growth;
- the level of expenses required to expand our sales and marketing activities;
- the level of research and development investment required to maintain and improve our technology;
- our need to acquire or license complementary technologies or acquire complementary businesses;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;

competing technological and market developments; and

changes in regulatory policies or laws that affect our operations.

We cannot be certain that additional capital will be available when and as needed or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in diagnostics companies or in the marketplace in general is limited due to the then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire, on acceptable terms, or at all. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to bad debts, inventories, valuation of intangibles and other long-term assets, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and our Registration Statement on Form S-1/A filed June 8, 2011 and there have been no material changes during the nine months ended September 30, 2011 or since the filing of our registration statement.

Contractual Obligations

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

On October 20, 2010, we entered into a licensing agreement for intellectual property. The agreement requires minimum payments of 1.0 million in four equal installments over two years and contains provisions for additional licensing fees of 1.25 million and additional royalties based on related product sales. The license terminates upon election by us as defined or termination of every patent and application of patent right included in the agreement or other material breach as defined in the contract.

On February 28, 2011, we entered into a 36 month operating lease for office equipment with total lease payments of $85,000. In conjunction with the lease, the lessor paid the Company approximately $27,000 to payoff previous contracts for similar equipment leased from a different vendor.

Off-Balance Sheet Arrangements

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

We have unutilized credit facilities with Square 1 Bank that provides a revolving line of credit up to $2.0 million and an unutilized equipment term loan totaling $1.0 million at September 30, 2011.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

our portfolio.

Interest Rate Risk

We have exposure to interest rate risk related to our variable rate borrowings. In 2010, we entered into a credit facility consisting of a revolving line of credit in the amount of $2.0 million and an equipment term loan in the amount of up to $2.0 million. In 2011, we amended the credit facility to provide an additional $1.0 million of borrowings to finance equipment purchases. As of September 30, 2011, we had no outstanding loans on the line of credit or the 2011 equipment loan increase and had drawn $2.0 million against the original 2010 equipment term loan. This loan bears an interest rate of 6.5%. As of September 30, 2011, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase in interest rates would have an insignificant pre-tax impact on our results of operations.

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Foreign Currency Exchange Risks

All of our operating facilities are located within the United States. We are a U.S. entity and our functional currency is the U.S. dollar. Virtually all of our revenues are based in the United States. In 2010, we entered into a licensing agreement for intellectual property that requires payment in Euros, and a small portion of our expenses in the first quarter of 2010, relating to our corporate office, were transacted in British pounds. We currently have no material operations outside of the United States which diminishes the extent of any foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

In the second quarter of 2011, we identified that some prior members of our finance and accounting department did not follow our internal control over financial reporting procedures. Specifically, members of our finance and accounting personnel did not effectively coordinate with members of our business development team regarding the terms of a license agreement. As a result of this failure, we failed to record certain intellectual property rights as both an asset and liability and, as a result, misstated our intangible assets in the periods identified in Note 8 to our condensed consolidated unaudited financial statements included in this quarterly report. In addition, in the second quarter of 2011, we identified that some prior members of our finance team misclassified a number of operating expenses as costs of goods sold and misclassified the current portion of a loan payable as long term debt. We believe that these misstatements and misclassifications, although immaterial to the prior periods in which they occurred, resulted from a deficiency in our internal control over financial reporting existing during these prior periods which constituted a material weakness in our internal control over financial reporting. Although the material weakness existed as of the fiscal year ended December 31, 2010, and as of the first quarter ended March 31, 2011, we did not discover the material weakness in our internal control over financial reporting until the second quarter of 2011, after the respective filing dates of our annual and quarterly reports. We believe the material weakness resulted from turnover in our finance and accounting departments, including turnover at the Chief Executive Officer and Chief Financial Officer level, resulting in improper training of prior members of our finance and accounting department to execute our internal control over financial reporting procedures.

Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed by us in reports that we file under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Our internal control over financial reporting are the controls, processes and procedures designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles. A deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

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Remediation of Material Weakness

Unrelated to the discovery of the material weakness, we had previously hired a new Chief Executive Officer, Chief Financial Officer and controller to lead our finance our accounting departments. Each of these individuals understands our system of internal controls, including our post-closing procedures which are designed to ensure our financial statements are prepared in accordance with generally accepted accounting principles. These new hires have also provided proper guidance and training on our internal control procedures to other finance and accounting personnel, many of which are also new hires. As a result, we have enhanced communication among our finance and accounting personnel and the personnel from our other departments. We believe these new hires will remediate the material weakness and that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented. No material weakness will be considered remediated, however, until any remedial procedures that we take have operated for an appropriate period, have been tested and management has concluded that they are operating effectively. In addition, we reviewed our processes and procedures for our internal control over financial reporting and we did not identify any additional controls with similar deficiencies. We have reviewed our assessment of the material weakness and our remediation and the status of its implementation and effectiveness with our audit committee.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of the end of the period covered by this quarterly report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2011, our disclosure controls and procedures were not effective due to the prior material weakness in our internal control over financial reporting that is still in process of being remediated and tested.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

During the second quarter and continuing into the third quarter, we implemented the changes to our disclosure controls and procedures and internal control over financial reporting described above. There were no other changes to our internal control over financial reporting during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

While our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance that their respective objectives will be met, we do not expect that our disclosure controls and procedures or our internal control over financial reporting are or will be capable of preventing or detecting all errors and all fraud. Any control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described under Item 1A of Part I of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed with the Securities and Exchange Commission on August 15, 2011, which updated and superseded the risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the Securities and Exchange Commission on March 11, 2011, together with all other information contained or incorporated by reference in this Quarterly Report on Form 10-Q before you decide to invest in our common stock. The risks described in our Annual Report on Form 10-K, as previously updated and superseded by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed with the Securities and Exchange Commission on August 15, 2011, have not materially changed. If any of the risks described in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2011 actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment.

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

Unregistered Sales of Equity Securities

None

Use of Proceeds from Registered Securities

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

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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ITEM 4. (REMOVED AND RESERVED).

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

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

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SIGNATURES

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

GENMARK DIAGNOSTICS, INC.

Date: November 14, 2011

/s/ Paul Ross
Paul Ross
Chief Financial Officer
(principal financial and accounting officer)

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EXHIBIT INDEX

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

10.30	Executive Employment Agreement, dated September 2, 2011, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Brad Calvin.
10.31	Executive Employment Agreement, dated October 10, 2011, by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. and Matthew R. Cohen.
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101*	XBRL Instance Document
101*	XBRL Taxonomy Extension Schema Document
101*	XBRL Taxonomy Calculation Linkbase Document
101*	XBRL Taxonomy Label Linkbase Document
101*	XBRL Taxonomy Presentation Linkbase Document

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