GenMark Diagnostics, Inc.
Form 10-Q
August 09, 2010
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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 June 30, 2010

¨ 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 ¨ No x

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

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

Large accelerated filer ¨ 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 July 31, 2010 was 11,723,512.

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	As of June 30, 2010	As of December 31, 2009
Current assets		
Cash and cash equivalents	$ 29,603,649	$ 16,482,818
Accounts receivable	437,457	169,842
Inventories	330,453	136,967
Other current assets	868,297	992,181
Total current assets	31,239,856	17,781,808
Property and equipment-net	1,779,418	1,381,618
Intangible assets-net of accumulated amortization	101,854	170,051
Other long-term assets	55,355	
Total assets	$ 33,176,483	$ 19,333,477
Current liabilities		
Accounts payable	$ 915,149	$ 1,504,905
Accrued compensation	1,277,483	822,388
Other current liabilities	1,439,335	886,032
Total current liabilities	3,631,967	3,213,325
Long-term liabilities		
Other non-current liabilities	814,512	795,334
Total liabilities	4,446,479	4,008,659

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Continued)

(Unaudited)

	As of June 30, 2010	As of December 31, 2009
Stockholders equity		
Ordinary shares, £0.23 ($0.3634 as of December 31, 2009) par value; -0- and 7,101,928 shares issued and outstanding as of June 30, 2010 and December 31, 2009, respectively		2,573,857
Deferred shares, £0.0099 ($0.01709 as of December 31, 2009) par value; -0- and 689,478,300 shares issued and outstanding as of June 30, 2010 and December 31, 2009, respectively		11,780,709
Common stock, $.0001 par value; 100,000,000 authorized; 11,723,512 and -0- issued and outstanding as of June 30, 2010 and December 31, 2009, respectively	1,172	
Preferred stock, $0.0001 par value; 5,000,000 authorized, none issued		
Additional paid-in capital	165,254,942	127,475,450
Accumulated deficit	(136,076,154)	(126,089,889)
Accumulated other comprehensive loss	(449,956)	(415,309)
Total stockholders equity	28,730,004	15,324,818
Total liabilities and stockholders equity	$ 33,176,483	$ 19,333,477

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Revenue				
Product sales	$ 523,197	231,068	$ 907,446	$ 408,979
License and other revenue	127,515	17,500	142,530	27,889
Total revenue	650,712	248,568	1,049,976	436,868
Cost of sales	862,285	732,281	1,429,681	2,106,842
Gross loss	(211,573)	(483,713)	(379,705)	(1,669,974)
Operating expenses				
Sales and marketing	1,203,672	741,461	2,261,957	1,295,414
Research and development	1,723,991	1,432,567	3,177,750	2,862,915
General and administrative	2,002,272	1,605,900	4,169,536	3,063,334
Total operating expenses	4,929,935	3,779,928	9,609,243	7,221,663
Loss from operations	(5,141,508)	(4,263,641)	(9,988,948)	(8,891,637)
Other income				
Foreign exchange (loss) gain		(7,196)	(1,110)	124,570
Interest income	4,172	3,599	8,826	26,296
Total other income	4,172	(3,597)	7,716	150,866
Loss before income taxes	(5,137,336)	(4,267,238)	(9,981,232)	(8,740,771)
Benefit (provision) for income taxes			(5,049)	59,089
Net loss	$ (5,137,336)	$ (4,267,238)	$ (9,986,281)	$ (8,681,682)
Net loss per share, basic and diluted	$ (0.60)	$ (1.08)	$ (1.28)	$ (2.22)
Weighted average number of shares outstanding	8,538,897	3,951,671	7,830,346	3,914,319
Condensed Consolidated statements of comprehensive loss three and six months ended June 30, 2010 and 2009				
Net loss	$ (5,137,336)	$ (4,267,238)	$ (9,986,281)	$ (8,681,682)
Foreign currency translation adjustment		(315,934)	(34,647)	(530,673)
Comprehensive loss	$ (5,137,336)	$ (4,583,172)	$ (10,020,928)	$ (9,212,355)

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Six Months Ended June 30,	
	2010	**2009**
Cash flows from operating activities:		
Net loss	$ (9,986,281)	$ (8,681,682)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	468,398	717,640
Loss from disposal of property and equipment		(10,000)
Impairment losses		549,148
Share-based compensation	812,302	95,957
Changes in operating assets and liabilities:		
Trade accounts receivable	(267,615)	(2,102)
Inventories	(127,679)	102,125
Other current assets	(224,720)	951,118
Accounts payable	(802,142)	(766,314)
Accrued compensation	455,095	(67,317)
Accrued and other liabilities	563,488	(538,400)
Net cash used in operating activities	(9,109,154)	(7,649,827)
Investing activities:		
Proceeds from the sale of property and equipment and intangible assets		10,000
Purchases of property and equipment	(574,828)	(446,511)
Net cash used in investing activities	(574,828)	(436,511)
Financing activities:		
Proceeds from issuance of ordinary shares and common stock	27,600,000	8,462,976
Costs incurred in conjunction with initial public offering	(4,752,986)	
Proceeds from stock option exercises	4,734	
Net cash provided by financing activities	22,851,748	8,462,976
Net increase in cash and cash equivalents	13,167,766	376,638
Cash and cash equivalents at beginning of period	16,482,818	8,822,458
Effect of foreign exchange rate changes	(46,935)	(377,306)
Cash and cash equivalents at end of period	$ 29,603,649	$ 8,821,790
Supplemental cash flow disclosures:		
Cash received (paid) for income taxes	$ (5,049)	$ 202,155
Cash received for interest	$ 8,826	$ 26,296
Noncash investing and financing activities:		
Reclassification of deposits on systems in other current assets, and inventory to property and equipment in 2010 and 2009, respectively	288,962	256,909
IPO Costs incurred but not paid	237,953	
Transfer of systems from property and equipment into inventory	65,806	

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) is a molecular diagnostics company focused on developing and commercializing the Company s proprietary e-sensor 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.

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

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.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As of June 30, 2009 the Company had $29,603,649 in cash and cash equivalents, working capital of $27,607,889 and an accumulated deficit of $136,076,154.

Management expects operating losses to continue through the foreseeable future until the Company has expanded its product offering and consequently increased its product revenues to an extent to cover the fixed cost base of the business. The management team has prepared cash flow forecasts which indicate, based on the current cash resources available and the availability of a line of credit of up to $4,000,000, signed during March 2010 that the Company has sufficient capital to fund its operations for at least the next twelve months.

Basis of Presentation

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 six months ended June 30, 2010 are not necessarily indicative of the results that may be expected for the year ending December 31, 2010. The information presented in the condensed consolidated financial statements and related footnotes at June 30, 2010, and for the six months ended June 30, 2010 and 2009, is unaudited and the condensed consolidated balance sheet amounts and related footnotes at December 31, 2009 have been derived from our audited financial statements. For further information, refer to the consolidated financial statements and accompanying footnotes included in the final prospectus relating to our initial public offering filed with the Securities and Exchange Commission (SEC) on June 1, 2010.

The Company evaluated subsequent events through August 9, 2010 the date of issuance of the unaudited condensed consolidated financial statements.

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.

During the three months ended June 30, 2010, the Company changed its functional currency from the British Pound to the U.S. Dollar.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 plant and equipment, incentive compensation, share-based compensation, inventory and intangible assets. Actual results could differ from those estimates.

New Accounting Pronouncements Adopted

In October 2009, authoritative guidance was provided on revenue arrangements with multiple deliverables. The guidance amended the accounting standards for multiple deliverable revenue arrangements to: (i) provide updated guidance on whether multiple deliverables exist, how the deliverables in an arrangement should be separated, and how the consideration should be allocated; (ii) require an entity to allocate revenue in an arrangement using estimated selling prices (ESP) of deliverables if a vendor does not have vendor-specific objective evidence of selling price (VSOE) or third-party evidence of selling price (TPE); and (iii) eliminate the use of the residual method and require an entity to allocate revenue using the relative selling price method.

Arrangements that contain multiple deliverables include sales of systems and test cartridges. These are accounted for as separate units of accounting if the following criteria are met: (i) the delivered item or items have value to the customer on a standalone basis and (ii) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. The Company considers a deliverable to have standalone value if the item is sold separately or if the item could be resold by the customer. The Company s revenue arrangements generally do not include a right of return for delivered products.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

The Company sold its first systems in the six months ended June 30, 2010. The Company elected to early adopt the new accounting guidance because it is able to meet the new separation criteria and has applied it to all applicable revenue arrangements entered into or materially modified beginning January 1, 2010. The adoption of the new guidance had an immaterial effect on the financial statements and on loss per share during the six months ended June 30, 2010.

The adoption of this guidance did not result in a change in the Company s units of accounting or in how the Company allocates arrangement consideration to its units of accounting, as the arrangements to which the new accounting guidance is applicable were first entered into during the six months ended June 30, 2010.

2. Share-Based Compensation

The Company recognizes share-based compensation expense related to share options and warrants issued to employees and directors in exchange for services. The compensation expense is based on the fair value of the awards, which are determined by utilizing various assumptions regarding the underlying attributes of the options and shares. The estimated fair value of options granted, net of forfeitures expected to occur during the vesting period, is amortized as compensation expense on an accelerated basis to reflect the vesting as it 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 respective function. The expense is derived from the Black-Scholes Option Pricing Model that uses several judgment based variables to calculate the expense. The inputs include the expected life of the option or warrant, the expected volatility and other factors.

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.

Employee participation is at the discretion of the compensation committee or senior management of the Company. All options 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 and 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 June 30, 2010, 815,582 shares remained available for future grant of awards under the Plan.

The following table summarizes stock option activity during the six months ended June 30, 2010:

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2009	993,214	$ 6.97
Granted	245,100	6.00
Exercised	(21,589)	(0.37)
Cancelled	(32,307)	(5.68)
Outstanding at June 30, 2010	1,184,418	$ 6.92

As of June 30, 2010, there were 318,477 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 7.39 years, and an aggregate intrinsic value of $0.

3. Revenue Recognition

The Company recognizes revenue from product sales and contract arrangements, net of discounts and sales related taxes. The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured.

The Company offers customers the choice to either purchase a system outright or to receive a system without an initial fee in exchange for an annual minimum purchase commitment for test cartridges. When a system is sold, revenue is generally recognized upon shipment of the unit. When a system is placed without an initial fee under a reagent rental agreement, the Company retains title to the equipment and the system remains capitalized on the balance sheet under property and equipment. Under the Company s reagent rental agreements, the Company retains the right to access or replace the systems at any time and customers pay an additional system rental fee for each test cartridge purchased. The reagent rental fee varies based on the monthly volume of test cartridges purchased.

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

We sell our durable systems and disposable test cartridges through a direct sales force in the United States. Components are individually priced and can be purchased separately or together. The system price is not dependent upon the purchase of any amount of disposable test cartridges. Revenue on system and test cartridge sales is recognized upon shipment, which is when title and the risk of loss and rewards of ownership have been transferred to the customer and there are no material other post-shipment obligations.

Arrangements that contain multiple deliverables include sales of systems and test cartridges. These are accounted for as separate units of accounting because the system has value to the customer on a standalone basis and the agreements generally do not include a right of return relative to delivered products. Revenue is allocated to each element based on a relative estimated selling price because the Company is unable to establish selling price using VSOE or TPE. Determination of ESP involves weighting several factors based on the specific facts and circumstances of each arrangement. The factors include, but are not limited to, geographies, market conditions, gross margin objectives, pricing practices and controls, customer segment pricing strategies and the product lifecycle. The Company analyzes selling prices used in their allocation of arrangement consideration on a quarterly basis, or more frequently if necessary.

During the six months ended June 30, 2010, the Company sold seven XT-8 systems.

Revenues related to royalties received from licenses are recognized evenly over the contractual period to which the license relates.

Shipping and handling costs are expensed as incurred and included in cost of product sales. In those cases where the Company bills shipping and handling costs to customers, the amounts billed are classified as revenue.

4. Fair Value of Financial Instruments

The carrying amount of the Company s financial instruments, including cash and cash equivalents, accounts receivable and accounts payable approximate their fair values. There were no significant financial instruments requiring one-time or recurring measurements of fair value during the six months ended June 30, 2010.

During the six months ended June 30, 2009, a cash flow analysis indicated that certain of the Company s patent licenses may have been impaired and required that an assessment of the fair value of the patent licenses be performed. These fair value measurements were done on the basis of unobservable Level 3 inputs, for which little or no market data exists. These inputs included the assumptions of future cash flows related to the items, and a discount rate applied to these cash flows. The assumed cash flows were projected based on management s best estimates for the remaining net cash flows for each item over its the estimated remaining useful life. Due to the relatively short-term period of future cash flows on these items, the use of a discount rate did not have a material impact on the valuation of these items. Impairments recorded during the six months ended June 30, 2009 as a result of these fair value measurements were $549,148 for intangible assets.

5. Net Loss Per Ordinary Share

The computations of diluted net loss per ordinary share for the six months ended June, 2010 and 2009 do not include the effects of the following options and warrants to acquire capital stock which were outstanding as of the end of each period as the inclusion of these securities would have been anti-dilutive.

	Six months ended June 30,	
	2010	2009
Share options	1,184,418	274,085
Warrants	88,317	
	1,275,735	274,085

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Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Share 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. At the same time, the warrant to purchase 88,317 of Osmetech s ordinary shares was converted to a warrant 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.

Additionally, Osmetech s deferred shares, which were created at the time of a 10-for-1 consolidation of ordinary shares on September 30, 2005 are excluded from basic and diluted net loss per ordinary share. Management considers these shares to be of minimal value. The deferred shares do not entitle the holder to payment of any dividend or other distribution or to receive notice or attend or vote at any general meeting of Osmetech. The deferred shares are non transferable. In the event of a return of assets on winding up of Osmetech, the deferred shareholders receive 1p in respect of their shareholding in its entirety.

6. Segment Information

The Company operates in one reportable segment, and substantially all of the Company s operations and assets are in the United States of America.

7. Property and Equipment, net

Property and equipment was comprised of the following as of June 30, 2010 and December 31, 2009:

	June 30, 2010	December 31, 2009
Property and equipment at cost:		
Plant, machinery and rental systems	$ 4,863,737	$ 4,274,115
Office equipment	1,295,441	1,079,214
Leasehold improvements	74,394	74,394
Total property and equipment at cost	6,233,572	5,427,723
Less accumulated depreciation	(4,454,154)	(4,046,105)
Net property and equipment	$ 1,779,418	$ 1,381,618

Depreciation expense amounted to $400,181 and $635,677 for the six months ended June 30, 2010 and 2009, respectively.

8. Note 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 June 30, 2010) 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. As of June 30, 2010, the Company has not drawn any funds under this loan and security agreement.

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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 six months ended June 30, 2010, 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, 2009, included in our final prospectus dated June 1, 2010 filed with the SEC. 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 predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading Risk Factors in Item 1A of Part II and elsewhere in this report. We undertake no obligation to revise or update publicly any forward-looking statement for any reason. Readers should carefully review the factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report and in Management s Discussion and Analysis of Financial Condition and Results of Operations , as well as in the documents filed by us with the SEC, as they may be amended from time to time, including our final prospectus dated June 1, 2010.

Results of Operations Three months ended June 30, 2010 compared to the three months ended June 30, 2009

Revenue

Revenue increased $402,000 or 162%, to $651,000 for the three months ended June 30, 2010 compared to $249,000 for the three months ended June 30, 2009. Revenue from product sales increased $292,000 or 126% to $523,000 for the three months ended June 30, 2010 compared to $231,000 for the three months ended June 30, 2009. The increase in revenue for the three months ended June 30, 2010 was partially driven by a $108,000 increase in system sales, compared to zero in the prior period, a $100,000 increase in other revenues related to a partnering contract and a $184,000 increase in reagent revenues, compared to $231,000 in the prior period, driven by an increase in our installed base of systems and an expanded menu of tests available for sale.

Cost of Sales and Gross Loss

Cost of sales increased $130,000, or 18%, to $862,000 for the three months ended June 30, 2010 compared to $732,000 for the three months ended June 30, 2009. The increase was primarily due to the increase in reagent and system revenues. Gross loss decreased $272,000 or 56% to $212,000 for the three months ended June 30, 2010 compared to $484,000 for the three months ended June 30, 2009. Higher revenues in the 2010 period were only slightly offset by higher manufacturing cost.

Sales and Marketing

Sales and marketing expense increased $462,000, or 62%, to $1.2 million for the three months ended June 30, 2010 compared to $741,000 for the three months ended June 30, 2009. The increase was driven by $318,000 in higher payroll related costs including salary, incentive, severance, recruiting and share based compensation, $75,000 in higher facility costs and $98,000 in higher marketing communications costs, partially offset by $157,000 in lower depreciation costs for promotional systems.

Research and Development

Research and development expense increased $291,000, or 20%, to $1.7 million for the three months ended June 30, 2010 compared to $1.4 million for the three months ended June 30, 2009. The increase was primarily due to a $187,000 increase for relocation costs associated with our new Carlsbad facility, $121,000 in development project supplies and $75,000 in higher facility costs.

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General and Administrative

General and administrative expense increased $396,000, or 25%, to $2.0 million for the three months ended June 30, 2010 compared to $1.6 million for the three months ended June 30, 2009. The increase was primarily due to $395,000 in higher payroll related costs including salary, fringe benefits, incentive, severance, and share-based compensation expense and $188,000 in higher legal costs partially offset by $328,000 in lower facility costs.

Other Income and Expense

Other income increased $8,000 to $4,000 for the three months ended June 30, 2010 compared to an expense of $4,000 for the three months ended June 30, 2009. There was no material foreign exchange gain or loss for the three months ended June 30, 2010 compared to $7,000 for the three months ended June 30, 2009. During the three months ended June 30, 2010 the Company completed the shutdown of its UK operations and changed its functional currency to the US dollar.

Interest and other income was flat at $4,000 for the three months ended June 30, 2010 compared to $4,000 for the three months ended June 30, 2009.

Benefit (Provision) for Income Taxes

No tax provisions were recorded for the three months ended June 30, 2010 or for the three months ended June 30, 2009. Due to the Company s losses it only records tax benefit or provisions related to minimum payments and refunds.

Loss per share

Loss per share decreased $0.48 to $0.60 for the three months ended June 30, 2010 compared to $1.08 for the three months ended June 30, 2009. Although net loss increased $870,000 or 20% to $5.1 million for the three months ended June 30, 2010 compared to $4.3 million for the three months ended June 30, 2009, the weighted average shares increased 4.6 million shares or 116% to 8.5 million shares for the three months ended June 30, 2010 as compared to 4.0 million shares for the three months ended June 30, 2009. The increase in weighted average shares was primarily due to the issuance of 4.6 million shares in connection with our June 3, 2010 IPO and a stock placement of 2.1 million shares in December 2009.

Results of Operations Six months ended June 30, 2010 compared to the six months ended June 30, 2009

Revenue

Revenue increased $613,000 or 140% to $1.0 million for the six months ended June 30, 2010 compared to $437,000 for the six months ended June 30, 2009. Revenue from product sales increased $498,000 or 122% to $907,000 for the six months ended June 30, 2010 compared to $409,000 for the six months ended June 30, 2009. The increase in revenue for the six months ended June 30, 2010 was partially driven by a $210,000 increase in system sales, compared to zero in the prior period, and a $288,000 increase in reagent revenues, compared to $409,000 in the prior period, driven by an increase in our installed base of systems and an expanded menu of tests available for sale.

Cost of Sales and Gross Loss

Cost of sales decreased $677,000, or 32%, to $1.4 million for the six months ended June 30, 2010 compared to $2.1 million for the six months ended June 30, 2009. The decrease was primarily due to a $549,000 write-down of unused content license intangibles during the first quarter of 2009 along with lower facility costs. Gross loss decreased $1.3 million or 77% to $380,000 for the six months ended June 30, 2010 compared to $1.7 million for the six months ended June 30, 2009 due to the higher revenues and lower costs in the 2010 period.

Sales and Marketing

Sales and marketing expense increased $1.0 million, or 75%, to $2.3 million for the six months ended June 30, 2010 compared to $1.3 million for the six months ended June 30, 2009. The increase was driven by $668,000 in higher payroll related costs including salary, incentive, severance, fringe and share based compensation, $150,000 in higher facility costs and $117,000 in higher marketing communications costs, partially offset by $208,000 in lower depreciation costs for promotional systems.

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Research and Development

Research and development expense increased $315,000, or 11%, to $3.2 million for the six months ended June 30, 2010 compared to $2.9 million for the six months ended June 30, 2009. The increase was primarily due to $90,000 in higher payroll related costs and $187,000 for relocation costs associated with our new Carlsbad facility, $65,000 in development project supplies and $150,000 in higher facility costs.

General and Administrative

General and administrative expense increased $1.1 million or 36%, to $4.2 million for the six months ended June 30, 2010 compared to $3.1 million for the six months ended June 30, 2009. The increase was primarily due to $1.0 million in higher payroll related costs including salary, fringe benefits, incentive, severance, and share based compensation share-based compensation expense and $283,000 in higher legal costs partially offset by $402,000 in lower facility costs.

Other Income and Expense

Other income and expense decreased $143,000 to $8,000 for the six months ended June 30, 2010 compared to $151,000 for the six months ended June 30, 2009. During the 2009 period, we realized a $125,000 gain on foreign exchange related to the strengthening of the U.S. dollar compared to the British Pound. We completed the shutdown of our UK operations during the six month period ending June 30, 2010 and changed our functional currency to the U.S. dollar.

Interest and other income declined $17,000 to $9,000 for the six months ended June 30, 2010 compared to $26,000 for the six months ended June 30, 2009, primarily due to lower interest rates.

Benefit (Provision) for Income Taxes

A tax provision of $5,000 was recorded for the six months ended June 30, 2010, compared to a tax benefit of $59,000 for the six months ended June 30, 2009. Due to our losses we only record tax provisions or benefit related to minimum payments and refunds.

Loss per share

Loss per share decreased $0.94 to $1.28 for the six months ended June 30, 2010 compared to $2.22 for the six months ended June 30, 2009. Although net loss increased $1.3 million or 15% to $10.0 million for the six months ended June 30, 2010 compared to $8.7 million for the six months ended June 30, 2009, the weighted average shares increased 3.9 million shares or 100% to 7.8 million shares for the six months ended June 30, 2010 compared to 3.9 million shares for the six months ended June 30, 2009. The increase in weighted average shares was primarily due to a stock placement of 2.1 million shares in December 2009 as well as the issuance of 4.6 million shares in connection with our June 3, 2010 IPO.

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability.

At June 30, 2010, we had $27.6 million of working capital, including $29.6 million in cash and cash equivalents.

Net cash used in operating activities increased $1.5 million to $9.1 million for the six months ended June 30, 2010 compared to $7.6 million for the six months ended June 30, 2009 primarily due to a $1.3 million increase in the net loss. The increase in the net loss for the current period was primarily related to a $716,000 increase in share based compensation. Other uses of operating cash include higher inventories and accounts receivable due to a higher revenue level and increased prepaid assets, partially offset by higher accrued compensation and other liabilities.

Net cash used in investing activities increased $138,000 to $575,000 for the six months ended June 30, 2010 compared to $437,000 for the six months ended June 30, 2009 primarily due to higher capitalized equipment amounts for XT-8 systems, $178,000 in equipment for our new Carlsbad facility and laboratory equipment for our development programs.

Net cash provided by financing activities increased $14.4 million to $22.9 million for the six months ended June 30, 2010 compared to $8.5 million for the six months ended June 30, 2009, primarily related to the June 3, 2010 closing of our initial public offering.

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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 June 30, 2010) 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.

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, however, the ratio is currently not applicable given that we have no bank indebtedness. 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. As of June 30, 2010, we had not drawn down any funds under the credit facility or the term loan, however, $500,000 of the availability under the credit facility was utilized as collateral for an outstanding letter of credit, reducing the availability from $2.0 million to $1.5 million. We are currently in compliance will all ratios and covenants.

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

Contractual Obligations

On February 8, 2010, we entered into a seven-year and seven-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 expansion rights and rights of first refusal for expansion within our building, subject to certain limitations.

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Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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

Foreign Currency Exchange Risks

Substantially 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. A small portion of our expenses in 2009 and the first quarter of 2010, relating to our corporate office, were transacted in British pounds. We anticipate having no material operations outside of the United States which will diminish the extent of any foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Our management has evaluated, with the participation of our principal executive and principal financial officers, the effectiveness of our disclosure controls and procedures as of June 30, 2010 and any change in our internal control over financial reporting that occurred during our second fiscal quarter ended June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Based on their evaluation, our principal executive and principal financial officers have concluded that these controls and procedures are effective as of June 30, 2010. There was no change in our internal control over financial reporting identified in connection with such evaluation that occurred during our second fiscal quarter ended June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Disclosure controls and procedures are our controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of assets, (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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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

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 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 events or developments 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.

Risks Related to Our Business

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. We obtained Food and Drug Administration, or FDA, clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We commenced offering our XT-8 systems and our Warfarin Sensitivity Test in July 2008. We commenced offering our Cystic Fibrosis Genotyping Test in July 2009 and our Thrombophilia Risk Test in April 2010. Our Respiratory Viral Panel Test is currently labeled for IUO. Our net losses from continuing operations were approximately $10.0 million for the six months ended June 30, 2010, $20.0 million in 2009 and $28.4 million in 2008. At June 30, 2010, we had an accumulated deficit of approximately $136.1 million. We will continue to incur significant expenses for the foreseeable future for our sales and marketing, research and development and regulatory activities and maintaining our existing and obtaining additional intellectual property rights. We can not provide you any assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our limited commercialization history and because the market for molecular diagnostic products is relatively new and rapidly evolving, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

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

Through June 30, 2010, we had primarily placed our XT-8 systems with customers at no initial charge through reagent rental agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years. While we also offer our XT-8 systems for sale, through June 30, 2010, we had sold only seven of our systems. We expect sales of our diagnostic tests associated with our XT-8 systems will account for the vast majority of our revenues for at least the next several years. We intend to dedicate a significant portion of our resources to the commercialization of our XT-8 system and our existing FDA-cleared diagnostic tests. Although we intend to develop a broad range of additional diagnostic tests for use with the XT-8 System and our next-generation AD-8 System, we can not assure you when or if we will obtain FDA clearances for the tests we intend to develop in the future, or whether the market will accept such new products. As a result, to the extent that our XT-8 System and our existing FDA-cleared diagnostic tests are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted and our business operating results and financial condition will be harmed.

We may fail to successfully expand the menu of diagnostic tests for our XT-8 System, or effectively predict the types of tests our existing and target customers want.

We currently market three FDA-cleared diagnostic tests and have developed one other diagnostic test currently labeled for IUO. In addition, we have eight diagnostic tests in the development or design stage. Some hospital-based and reference laboratories may not consider adopting our XT-8 System until we offer a broader menu of diagnostic tests. Although we are developing additional tests to respond to the needs of these laboratories, we can not guarantee that we will be able to license the appropriate technology, or develop and obtain required regulatory clearances or approvals, for enough additional tests quickly enough or in a manner that is cost-effective. The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, in order to commercialize our products, we are required to undertake time consuming and costly

development activities, including clinical studies for which the outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to successfully develop and commercialize additional diagnostic tests for use with our XT-8 system, our revenues and our ability to achieve profitability will be impaired.

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

Our future success depends on the acceptance by our target customers, third-party payors and the medical community that our molecular diagnostic products are a reliable, accurate and cost-effective replacement for other molecular diagnostic testing methods. Physician offices and many hospitals outsource their molecular diagnostic testing needs to national or regional reference laboratories. Our business success depends on our ability to convince our target reference laboratories and hospitals to replace their current testing methods with our XT-8 System and related diagnostic tests and increase usage of our new tests on installed systems. Many factors may affect the market acceptance and commercial success of our molecular diagnostic technology and products, including:

- our ability to convince our potential customers of the advantages and economic value of our diagnostic systems and tests over competing technologies and products;
- the relative convenience and ease of testing of our diagnostic systems over competing products;
- the introduction of new technologies and competing products that may make our technologies and products a less attractive solution for our target customers;
- the breadth of our menu of available diagnostic tests relative to our competitors;
- our success in training reference and hospital-based laboratories on the proper use of our products;
- the willingness of third-party payors to reimburse laboratories that use our diagnostic systems and tests;
- the acceptance in the medical community of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

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

We primarily place our XT-8 systems with customers at no direct charge through reagent rental agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years. While we also offer our XT-8 systems for sale, through June 30, 2010, we had sold only seven systems and the amount of additional capital we may need to raise depends on the amount of our revenues from sales of test cartridges sold through these reagent rental agreements. We do not currently sell enough test cartridges to recover all of our fixed manufacturing expenses associated with the production of our systems and test cartridges and therefore we currently have a high cost of sales relative to revenue, resulting in a gross loss. If we continue not to sell a sufficient number of test cartridges to offset our expenses associated with these reagent rental agreements, our liquidity will be adversely affected.

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

We have limited marketing, sales and distribution experience and capabilities. In connection with our XT-8 System, we commenced offering our Warfarin Sensitivity Test in July 2008, our Cystic Fibrosis Genotyping Test in July 2009 and our Thrombophilia Risk Test in April 2010. As of June 30, 2010, we had 39 systems actively in use with customers. We recently adjusted our sales strategy by terminating our relationship with a third-party distributor and beginning to build our own direct sales force. Our ability to achieve profitability depends on attracting customers for the XT-8 System and building brand loyalty. To successfully perform sales, marketing, distribution and customer support functions ourselves, we will 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.

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

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

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

- the expenses we incur in connection with commercialization activities, including product marketing, sales and distribution;
- the expenses we incur in licensing biomarkers from third parties to expand the menu of diagnostics tests we plan to offer;
- our sales strategy and whether the revenues from sales of our test cartridges or XT-8 systems will be sufficient to offset our expenses;
- the time and resources required to develop, conduct clinical studies and obtain regulatory clearances for the additional diagnostic tests we develop;
- the expenses we incur for research and development required to maintain and improve our technology, including developing our next-generation molecular diagnostic system;
- the costs to attract and retain personnel with the skills required for effective operations; and
- 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.

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

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

We compete with companies that design, manufacture and market already-existing and new molecular diagnostics systems and tests. These competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, such as Luminex Corporation and Nanosphere, Inc.;
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods; and

healthcare companies that manufacture laboratory-based tests and analyzers, such as Roche Diagnostics and Qiagen NV.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and our competitors improve their current products and expand their menu of diagnostic tests. One or more of our competitors may offer technology superior to ours and render our technology or our current products obsolete, unattractive or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable.

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

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

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

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

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 substantial product revenues, we will be required to finance our operations with our existing cash resources. We may need to raise additional funds in the future to support our operations. We can not be certain that additional capital will be available as needed or on acceptable terms, or at all. If we require additional capital at a time when investment in molecular diagnostics companies or in 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 and these newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. If we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we could be required to relinquish significant rights to our technologies, products or grant licenses on terms that are not favorable to us.

Manufacturing risks and inefficiencies may adversely affect our ability to produce products.

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. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on inventory levels, current market trends and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our products, there could be significant differences between our estimates and the actual amounts of products we require.

We currently manufacture our proprietary test cartridges at our Carlsbad, California manufacturing facility. We outsource manufacturing of our XT-8 system and much of the disposable component molding and component assembly for our test cartridges. Our XT-8 system is manufactured by Aubrey Group Inc., our single source supplier that specializes in contract design and manufacturing of electronic and electromechanical devices for medical use. The components are custom-made by only a few outside vendors. Reliance on third-party manufacturers entails risks 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; and
- 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.

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

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

We may not be successful in developing our next-generation AD-8 System.

We are developing our next-generation platform, the AD-8 System. We are designing the AD-8 System to integrate sample preparation with our eSensor technology to allow technicians to be able to place a minimally prepared patient sample into our test cartridge and obtain results with no additional steps. The development of the AD-8 System is a complex process, and we may not be successful in completing the development of all the currently intended features and benefits of the AD-8 System, which may limit its marketability. In addition, before commercializing the AD-8 System we will be required to obtain regulatory approval for the AD-8 System as well as each of the diagnostic tests to be used on the AD-8 System, including those tests that previously received approval for use with our XT-8 systems. If we are unable to successfully develop and obtain regulatory approval for our AD-8 System and related diagnostic tests, our business plan will be impaired.

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

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

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

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

Assuming we receive the applicable regulatory approvals, we intend to market our diagnostic products outside the United States through third-party distributors. These distributors may not commit the necessary resources to market and sell our products to the level of our expectations. If distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or we are unable to locate distributors in particular geographic areas, our ability to realize long-term international revenue growth would be materially adversely affected.

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 of other countries regarding safety and efficacy and governing, among other things, clinical studies and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. The regulatory approval process outside the United States may include all of the risks associated with obtaining FDA approval, as well as additional risks. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all.

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

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

- fluctuations in currency exchange rates;
- unexpected changes in foreign regulatory requirements;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards;
- increased financial accounting and reporting burdens and complexities;
- political, social and economic instability abroad, terrorist attacks and security concerns in general; and
- reduced or varied protection for intellectual property rights in some countries.

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

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 and 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 can not eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. 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 can not 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.

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

Our success depends on the market s confidence that we can provide reliable, high-quality diagnostics systems. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. As a result, our reputation and the public image of our products or technologies will be impaired if our products fail to perform as expected. Although our diagnostic systems are designed to be user-friendly, the functions they perform are quite complex, and our products may develop or contain undetected defects or errors. If we experience a sustained material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development and management resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could materially harm our business.

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We also face an inherent 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 up to an annual aggregate limit of $7.0 million. 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 would have to be paid out of our cash reserves, which would have a detrimental effect on our financial condition. It is difficult to determine whether we have obtained sufficient insurance to cover potential claims. Also, we can not assure you that we can or will maintain our insurance policies on commercially acceptable terms, or at all. A product liability claim could have a material adverse effect on our business, financial condition and results of operations.

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

As of December 31, 2009, we had net operating loss carryforwards of approximately $62.5 million for U.S. federal tax purposes. These loss carryforwards will expire in varying amounts through 2029. To the extent these net operating loss carryforwards are available, we intend to use them to reduce the corporate income tax liability associated with our operations. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. As a result, prior or future changes in ownership could put limitations on the availability of our net operating loss carryforwards. To the extent our use of net operating loss carryforwards is significantly limited, our income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards, which could result in lower profits. We also had non-U.S. net operating loss carryforwards of approximately $30.4 million as of December 31, 2009. As a result of the Reorganization, there is a significant risk these non-U.S. net operating loss carryforwards may not be utilized.

Risks Related to Regulation

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

We are investing in the research and development of new diagnostic tests to expand our menu of testing options, as well as to develop our next-generation AD-8 System, which we anticipate will reduce the need for sample preparation when using our system. Our products are subject to 510(k) clearance or pre-market approval by the FDA prior to their marketing for commercial use in the United States, and to any approvals required by foreign governmental entities prior to their marketing outside the United States. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510(k) clearance, pre-market approval, or foreign regulatory approvals.

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

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

Our manufacturing processes and facilities, and those of some of our contract manufacturers, are required to comply with the federal Quality System Regulation, or the 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 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.

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

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

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our products;
- total or partial suspension of production or distribution;
- the FDA s refusal to grant pending future clearance or pre-market approval for our products;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the import or export of our products; and
- criminal prosecution.

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

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

The use of our diagnostic products by our customers is also affected by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance and quality control and inspections. Current or future CLIA requirements or the

promulgation of additional regulations affecting laboratory testing may prevent some laboratories from using some or all of our diagnostic products.

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

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

a covered benefit under its health plan;

appropriate and medically necessary for the specific indication;

cost effective; and

neither experimental nor investigational.

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

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.

In the United States, the American Medical Association assigns specific Current Procedural Terminology, or CPT, codes, which are necessary for reimbursement of diagnostic tests. Once the CPT code is established, the Centers for Medicare and Medicaid Services establish reimbursement payment levels and coverage rules under Medicaid and Medicare, and private payors establish rates and coverage rules independently. We can not 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 and Medicaid or any third-party payor. Third-party payors may nonetheless choose to reimburse our customers on a per test basis based on individual biomarker detection, rather than on the basis of the number of results given by the test. This may result in reference laboratories, public health institutions and hospitals electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, these entities may purchase separate tests for each disease, rather than products that can be used to return multiple test results.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Increasingly, Medicare, Medicaid and other third-party payors are challenging the prices charged for medical services, including clinical diagnostic tests. In addition, Medicare s current freeze on its clinical laboratory fee schedule may adversely affect the growth of the molecular diagnostics market for patients in the United States who are over 65 or have specific disabilities. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for our products, which in turn, could negatively impact pricing. 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.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products and to produce, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, in the future, the FDA may require more burdensome premarket approval of our system or diagnostic tests rather than the 501(k) clearance process we have used to date and anticipate primarily using in the future. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, financial condition and results of operations.

Federal and state governments in the United States are also undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted comprehensive health care reform legislation known as the Patient Protection and Affordable Care Act of 2010, or the PPACA. While the PPACA involves expanding coverage to more individuals, it includes new regulatory mandates and other measures designed to constrain medical costs. The PPACA also imposes significant new taxes on medical device manufacturers that are expected to cost the medical device industry up to $20 billion over the next decade. There are also stringent new reporting requirements of financial relationships between device manufacturers and physicians and teaching hospitals. Complying with PPACA could significantly increase our costs and adversely affect our business and financial condition.

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Our operations will also be impacted by the federal Patient Protection and Affordable Care Act of 2010, as modified by the Health Care and Education Reconciliation Act of 2010, which we refer to as the Health Care Act. The Health Care Act imposes a 2.3% excise tax on sales of medical devices by manufacturers. Taxable devices include any medical device defined in section 201(h) of the Federal Food, Drug and Cosmetic Act, or 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 expect to begin paying the tax in 2013. The Health Care Act also requires manufacturers to report to the Department of Health and Human Services detailed information about financial arrangements with physicians and teaching hospitals. These reporting provisions preempt state laws that require reporting of the same information, but not those that require reports of different or additional information. Failure to comply subjects the manufacturer to significant civil monetary penalties. We expect compliance with the Health Care Act to impose significant administrative and financial burdens on 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 FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely have a material adverse effect on our business, financial conditions and results of operations.

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 negatively affect our business.

Risks Related to Our Intellectual Property

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

We are exposed to, and may be threatened with, litigation by third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. Some of these third parties may be better capitalized and have more resources than us. In addition, in order to commercialize certain new or existing tests including our Thrombophilia Risk Test, we may be required to license certain biomarkers or risk that a third party may claim that the use of certain biomarkers in our tests infringes their intellectual property rights. We have received correspondence in the past bringing to our attention certain patent rights held by third parties and offering to discuss licensing terms to the patents. Some of these letters relate to patents that are important to our products. Independently, we have also identified patents held by third parties that cover one or more of our products or planned products. Although we have taken licenses to numerous such third-party patents, we have also declined to license certain patents in instances where we do not believe our existing products infringe valid claims. If one of these patents was found to be valid and cover any of our products, proprietary technologies or their uses, we or any collaborator could be enjoined by a court and required to pay damages and could be unable to commercialize our products or product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or any collaborator on acceptable terms, or at all, which could potentially prevent us from selling our current products or developing new tests. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away. Furthermore, such litigation is costly and could affect our results of operations and divert the attention of managerial and technical personnel.

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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 132 issued U.S. and foreign patents which we own directly or for which we are the exclusive licensee and that expire between 2013 and 2021. However, patents may not be issued based on any pending or future patent applications owned by or licensed to us and, moreover, issued patents owned or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

We have also licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We can not 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 can not be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents.

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

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

- others may be able to make systems or devices that are similar to ours but that are not covered by the claims of our patents;
- we may not be able to identify potential infringers of our technology due in part to the large number of competitors in the field;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- our pending patent applications may not result in issued patents;

our issued patents may not provide us with any competitive advantages or may be held invalid or unenforceable as a result of legal challenges by third parties;

the claims of our issued patents or patent applications when issued may not cover our device or product candidates;

there may be dominating patents relevant to our product candidates of which we are not aware;

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

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

we may not develop additional proprietary technologies that are patentable.

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

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

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

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

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party s activities do not infringe our patents. In addition, the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have recently changed some tests regarding granting patents and assessing the validity of patent claims. As a consequence, issued patents may be found to contain invalid claims according to the newly revised and currently evolving standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a re-examination proceeding before the PTO, or during litigation, under the revised criteria which make it more difficult to obtain patents.

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

- fluctuations in our operating results or the operating results of our competitors;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- failure of our products to achieve or maintain market acceptance or commercial success;
- conditions and trends in the markets we serve;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- changes in our pricing policies or the pricing policies of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

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

Some of our existing stockholders can exert control over us and may not make decisions that are in the best interests of all stockholders.

As of June 30, 2010, officers, directors, and stockholders holding more than 5% of Genmark s outstanding shares collectively controlled a significant amount of our outstanding shares of common stock based on their respective beneficial ownership. As a result, these stockholders, if they act together, would be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Accordingly, this concentration of ownership may harm the market price of our shares by delaying or preventing a change in control of us, even if a change is in the best interests of our other stockholders. In addition, the interests of this concentration of ownership may not always coincide with the interests of other stockholders, and accordingly, they could cause us to enter into transactions or agreements that we would not otherwise consider.

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

A substantial portion of our outstanding common stock can be traded without restriction at any time. Some of these shares are currently restricted as a result of securities laws or lock-up agreements that were entered into with the underwriters of our public offering, but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We currently intend to invest our future earnings, if any, to fund the development and growth of our business. In addition, our credit facility restricts our ability to pay dividends. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt agreements we may enter into and other factors our board of directors may deem relevant. If we do not pay dividends, your ability to achieve a return on your investment in our company will depend on any future appreciation in the market price of our common stock. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our holders have purchased their common stock.

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

As a public company in the United States, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Our first report on compliance with Section 404 is expected to be in connection with our financial statements for the year ending December 31, 2011. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting. Our independent registered public accounting firm s audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of our internal control over financial reporting. Accordingly, no such opinion was expressed. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate. Even after we develop these new procedures additional weaknesses in our internal control over financial reporting may be discovered. In order to fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities such as the SEC or NASDAQ and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we or our auditors are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404 we may be subject to sanctions or investigations by regulatory authorities such as the SEC or NASDAQ and we could lose investor confidence in the accuracy and completeness of our financial reports, which would have a material adverse effect on our business and on the price of our common stock and our ability to access the capital markets.

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

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

Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, 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 only remove our directors for cause;
- establish a classified board of directors, such that not all members of the board of directors may be elected at one time;
- authorize our board of directors to issue without stockholder approval up to 100,000,000 shares of common stock, that, if issued, would dilute our stock ownership and could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- authorize our board of directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the board of directors that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and

require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

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

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

Unregistered Sales of Equity Securities

During the period from April 1, 2010 until June 30, 2010, we granted options to purchase 245,100 shares of common stock at an exercise price of $6.00 per share. These securities were issued pursuant to written compensatory plans or arrangements with our employees and directors in reliance on the exemptions provided by either Section 4(2) of the Securities Act or Rule 701 promulgated under Section 3(b) of the Securities Act.

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 $24.0 million in net proceeds after deducting underwriting discounts and commissions of $1.9 million and other offering expenses of $1.7 million. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on June 1, 2010 pursuant to Rule 424(b). We invested the funds received in registered money market funds.

Item 3. DEFAULTS UPON SENIOR SECURITIES.

None.

Item 4. (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: August 9, 2010

/s/ STEVEN J. KEMPER
Steven J. Kemper

Chief Financial Officer

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EXHIBIT INDEX

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

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.