GenMark Diagnostics, Inc.
Form 10-Q
August 15, 2011
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2011

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

For the transition period from to

Commission File Number: 001-34753

GenMark Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

The number of outstanding shares of the registrant s common stock on August 3, 2011 was 20,474,570.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I- FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

(Unaudited)

	As of June 30, 2011	As of December 31, 2010
Current assets		
Cash and cash equivalents	$ 43,517	$ 18,329
Accounts receivable, net of allowance of $87 and $39 at June 30, 2011 and December 31, 2010, respectively	640	678
Inventories	1,206	897
Other current assets	495	2,193
Total current assets	45,858	22,097
Property and equipment, net	3,195	2,702
Intangible assets, net	1,403	1,460
Other long-term assets	80	55
Total assets	$ 50,536	$ 26,314
Current liabilities		
Accounts payable	$ 2,866	$ 823
Accrued compensation	1,288	1,172
Current portion of loan payable	917	
Other current liabilities	1,575	1,945
Total current liabilities	6,646	3,940
Long-term liabilities		
Loan payable	1,083	
Other non-current liabilities	1,083	1,307
Total liabilities	$ 8,812	$ 5,247
Stockholders equity		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued		
Common stock, $0.0001 par value; 100,000 authorized; 20,475 and 11,724 issued and outstanding as of June 30, 2011 and December 31, 2010, respectively	2	1
Additional paid-in capital	198,951	166,009
Accumulated deficit	(156,715)	(144,493)
Accumulated other comprehensive loss	(514)	(450)
Total stockholders equity	41,724	21,067
Total liabilities and stockholders equity	$ 50,536	$ 26,314

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Product Revenue	$ 866	$ 523	$ 1,559	$ 907
License and other revenue	35	142	100	168
Total revenue	901	665	1,659	1,075
Cost of sales	1,294	749	2,795	1,249
Gross loss	(393)	(84)	(1,136)	(174)
Operating expenses				
Sales and marketing	1,220	1,285	2,439	2,394
General and administrative	1,810	2,015	3,933	4,195
Research and development	2,292	1,757	4,856	3,226
Total operating expenses	5,322	5,057	11,228	9,815
Loss from operations	(5,715)	(5,141)	(12,364)	(9,989)
Other income				
Other income (expense)	174		186	(1)
Interest income (expense)	(27)	4	(21)	9
Total other income	147	4	165	8
Loss before income taxes	(5,568)	(5,137)	(12,199)	(9,981)
Provision for income taxes	12		23	5
Net loss	$ (5,580)	$ (5,137)	$ (12,222)	$ (9,986)
Net loss per share, basic and diluted	$ (0.39)	$ (0.60)	$ (0.93)	$ (1.28)
Weighted average number of shares outstanding	14,366	8,539	13,076	7,830
Condensed consolidated statements of comprehensive loss three and six months ended June 30, 2011 and 2010				
Net loss	$ (5,580)	$ (5,137)	$ (12,222)	$ (9,986)
Foreign currency translation adjustment	(64)		(64)	(35)
Comprehensive loss	$ (5,644)	$ (5,137)	$ (12,286)	$ (10,021)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2011	**2010**
Cash flows from operating activities:		
Net loss	$ (12,222)	$ (9,986)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	622	468
Share-based compensation	1,227	812
Changes in operating assets and liabilities:		
Trade accounts receivable	38	(268)
Inventories	(275)	(128)
Other current assets	1,673	(224)
Accounts payable	1,443	(802)
Accrued compensation	92	455
Accrued and other liabilities	(591)	564
Net cash used in operating activities	(7,993)	(9,109)
Investing activities:		
Payments for intellectual property licenses	(365)	
Purchases of property and equipment	(609)	(575)
Net cash used in investing activities	(974)	(575)
Financing activities:		
Proceeds from issuance of ordinary shares and common stock	34,532	27,600
Costs incurred in conjunction with public offering	(2,377)	(4,752)
Proceeds from borrowings	2,000	
Proceeds from stock option exercises		4
Net cash provided by financing activities	34,155	22,852
Effect of foreign exchange rate changes		(47)
Net increase in cash and cash equivalents	25,188	13,121
Cash and cash equivalents at beginning of period	18,329	16,483
Cash and cash equivalents at end of period	$ 43,517	$ 29,604

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Genmark Diagnostics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

(unaudited)

1. Organization and basis of presentation

Genmark Diagnostics, Inc. (the Company or GenMark) is a molecular diagnostics company focused on developing and commercializing the Company s proprietary 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.

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

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

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

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

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

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

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

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

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and has an accumulated deficit of $156.7 million at June 30, 2011. Cash and cash equivalents at June 30, 2011 were $43.5 million.

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

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

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

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

Recent Accounting Pronouncements

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

Table of Contents

Fair Value of Financial Instruments

The Company s financial instruments consist of cash equivalents, accounts receivable, accounts payable and loan payable. The carrying amounts of accounts receivable, accounts payable and the loan payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments. There were no significant financial instruments requiring one-time or recurring measurements of fair value during the six months ended June 30, 2011.

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

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

Non-recurring measurements: The Company measures the fair value of its long-lived assets on a periodic basis when it appears that there may be requirement to do so, such as an indication of impairment. There was no impairment recorded for the six months ended June 30, 2011.

Income Taxes

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

Corporate Reorganization

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

2. Share-Based Compensation

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

5

Table of Contents

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

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

Options are generally exercisable for a period up to 10 years after grant and are forfeited if the employee leaves the Company before the options vest. As of June 30, 2011, 145,948 shares remained available for future grant of awards under the Plan. Restricted stock grants reduce the amount of stock options available for grant under the 2010 Plan and are excluded from the table below.

The following table summarizes stock option activity during the six months ended June 30, 2011:

	Number of Share options	Weighted average exercise price
Outstanding at December 31, 2010	1,107,920	$ 6.40
Granted	665,000	$ 4.30
Exercised		
Cancelled	(181,555)	$ 5.59
Outstanding at June 30, 2011	1,591,365	$ 5.46
Exercisable at June 30, 2011	529,104	$ 6.69

As of June 30, 2011, there were 1,433,137 options that are vested or expected to vest and these options have a remaining weighted average contractual term of 8.74 years, and an aggregate intrinsic value of $1,124,234.

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

Expected volatility (%)	70.00
Expected life (years)	6.08
Risk free rate (%)	2.53
Expected dividend yield (%)	0.00
Estimated forfeitures (%)	5.00

During the six months ended June 30, 2011, the Company granted 411,169 shares of restricted stock to employees and 10,000 shares of restricted stock to an outside consultant. The restricted stock granted to employees generally vests over a four year period except for 4,000 shares of restricted stock issued to one employee as part of a separation agreement that vested on May 31, 2011 and 222,926 shares issued to senior management employees that vested May 5, 2011. The restricted stock granted to the outside consultant vested on March 1, 2011 commensurate with the period of service rendered to the Company.

3. Net Loss per Common Share

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

Table of Contents

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

	June 30,	
	2011	2010
Weighted average stock options	1,520	1,184
Warrants	88	88
Restricted Stock unvested, issued and held in escrow	446	
	2,054	1,272

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

4. Property and Equipment, net

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

	June 30, 2011	December 31, 2010
Property and equipment at cost:		
Plant and machinery	$ 2,474	$ 2,452
Rental systems	3,837	2,822
Office equipment	1,548	1,542
Leasehold improvements	536	596
Total property and equipment at cost	8,395	7,412
Less accumulated depreciation	(5,200)	(4,710)
Net property and equipment	$ 3,195	$ 2,702

Depreciation expense amounted to $564,000 and $400,000 for the six months ended June 30, 2011 and 2010, respectively.

5. Loan payable

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

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

As of June 30, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had drawn $2.0 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% are due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that are then outstanding shall be payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

Pursuant to the terms of the loan and security agreement, we are required to maintain a ratio of liquidity to bank indebtedness equal to at least 1.50 to 1.00. In addition, the loan and security agreement includes several restrictive covenants, including requirements that we obtain the consent of Square 1 Bank prior to entering into any change of control event unless all debt is repaid to Square 1 Bank prior

Table of Contents

to the change of control event, incurring other indebtedness or liens with respect to our property, making distributions to our stockholders, making certain investments or entering into certain transactions with affiliates and other restrictions on storing inventory and equipment with third parties. The agreement also limits the amount we can borrow under the term loan to license genetic biomarkers to $500,000. To secure the credit facility, we granted Square 1 Bank a first priority security interest in our assets and intellectual property rights. We are currently in compliance will all ratios and covenants.

6. Income taxes

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

As of June 30, 2011, the Company has recorded a full valuation allowance against all of its net deferred tax assets due to the uncertainty surrounding the Company s ability to utilize these assets in the future. Provision for income tax was $23,000 and $5,000 for the six months ended June 30, 2011 and 2010, respectively. Due to the Company s losses it only records tax provision or benefit related to minimum tax payments or refunds and interest and penalties related to its uncertain tax positions.

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

The total balance of accrued interest related to uncertain tax positions was $117,000 as of June 30, 2011. The Company recognizes interest and penalties related to uncertain tax positions as a component of income tax expense. The Company does not expect its unrecognized tax benefits to change significantly over the next twelve months.

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

7. Common stock offering

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

8. Unrecorded licensing agreement and reclassifications

Subsequent to the issuance of the 2010 audited financial statements, the Company concluded that a contract for the purchase of certain intellectual property rights should have been recorded as both an asset and a liability in the financial statements for the periods ended December 31, 2010 and March 31, 2011. The Company has recorded this contract which results in an increase of $1,389,000 to intangible assets for the year ended December 31, 2010 and for the period ended March 31, 2011, respectively. The current and long-term portion of the liability for the contract was $695,000 and $694,000 and $1,043,000 and $346,000 respectively as of December 31, 2010 and March 31, 2011. As of June 30, 2011, the current and long-term portion of the obligation for the contract was $726,000 and $363,000 respectively.

Subsequent to the issuance of the 2010 audited financial statements, the Company further concluded that certain expenses were classified incorrectly in its Consolidated Statements of Operations for the past periods presented herein, with no net impact to operating income, net loss, statements of cash flows or balance sheets. The Company has corrected these immaterial misstatements. These corrections result in reductions to cost of sales of $113,000 and $181,000 in the quarter and six-month period ending June 30, 2010 and $142,000 in the six-month period ending June 30, 2011 and corresponding increases to sales and marketing and research and development expenses.

Additionally, based on a loan amendment dated March 2011, the Company should have reclassified $667 of its loan payable to current portion of long-term debt at March 31, 2011. The Company corrected this presentation as of June 30, 2011.

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

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

(unaudited)

	As Reported December 31, 2010	Adjustment	As Corrected December 31, 2010
Current assets			
Cash and cash equivalents	$ 18,329		$ 18,329
Accounts receivable, net of allowance of $87 and $39 at June 30, 2011 and December 31, 2010, respectively	678		678
Inventories	897		897
Other current assets	2,193		2,193
Total current assets	22,097		22,097
Property and equipment, net	2,702		2,702
Intangible assets, net	71	1,389	1,460
Other long-term assets	55		55
Total assets	$ 24,925	$ 1,389	$ 26,314
Current liabilities			
Accounts payable	$ 823		$ 823
Accrued compensation	1,172		1,172
Other current liabilities	1,250	695	1,945
Total current liabilities	3,245	695	3,940
Long-term liabilities			
Loan payable			
Other non-current liabilities	613	694	1,307
Total liabilities	$ 3,858	$ 1,389	$ 5,247
Stockholders equity			
Preferred stock, $0.0001 par value; 5,000 authorized, none issued			
Common stock, $0.0001 par value; 100,000 authorized; 20,475 and 11,724 issued and outstanding as of June 30, 2011 and December 31, 2010, respectively	1		1
Additional paid-in capital	166,009		166,009
Accumulated deficit	(144,493)		(144,493)
Accumulated other comprehensive loss	(450)		(450)

Total stockholders equity	21,067		21,067
Total liabilities and stockholders equity	$ 24,925	$ 1,389	$ 26,314

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	As Reported		Adjustments	As Corrected	
	Three Months Ended June 30,		Three Months Ended June 30,	Three Months Ended June 30,	
	2011	2010	2010	2011	2010
Product Revenue	$ 866	$ 523	$	$ 866	$ 523
License and other revenue	35	128	14	35	142
Total revenue	901	651	14	901	665
Cost of sales	1,294	862	(113)	1,294	749
Gross loss	(393)	(211)	127	(393)	(84)
Operating expenses					
Sales and marketing	1,220	1,204	81	1,220	1,285
General and administrative	1,810	2,002	13	1,810	2,015
Research and development	2,292	1,724	33	2,292	1,757
Total operating expenses	5,322	4,930	127	5,322	5,057
Loss from operations	(5,715)	(5,141)		(5,715)	(5,141)
Other income					
Other income (expense)	174			174	0
Interest income (expense)	(27)	4		(27)	4
Total other income	147	4		147	4
Loss before income taxes	(5,568)	(5,137)		(5,568)	(5,137)
Provision for income taxes	(12)			(12)	0
Net loss	$ (5,580)	$ (5,137)	$	$ (5,580)	$ (5,137)
Net loss per share, basic and diluted	$ (0.39)	$ (0.60)		$ (0.39)	$ (0.60)
Weighted average number of shares outstanding	14,366	8,539		14,366	8,539
Condensed consolidated statements of comprehensive loss three and six months ended June 30, 2011 and 2010					
Net loss	$ (5,580)	$ (5,137)		$ (5,580)	$ (5,137)
Foreign currency translation adjustment	(64)			(64)	
Comprehensive loss	$ (5,644)	$ (5,137)		$ (5,644)	$ (5,137)

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

(Unaudited)

	As Reported		Adjustments		As Corrected	
	Six Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010	2011	2010
Product Revenue	$ 1,559	$ 907	$	$	$ 1,559	$ 907
License and other revenue	106	143	(6)	25	100	168
Total revenue	1,665	1,050	(6)	25	1,659	1,075
Cost of sales	2,937	1,430	(142)	(181)	2,795	1,249
Gross loss	(1,272)	(380)	136	206	(1,136)	(174)
Operating expenses						
Sales and marketing	2,350	2,262	89	132	2,439	2,394
General and administrative	3,921	4,169	12	26	3,933	4,195
Research and development	4,821	3,178	35	48	4,856	3,226
Total operating expenses	11,092	9,609	136	206	11,228	9,815
Loss from operations	(12,364)	(9,989)			(12,364)	(9,989)
Other income						
Other income (expense)	186	(1)			186	(1)
Interest income (expense)	(21)	9			(21)	9
Total other income	165	8			165	8
Loss before income taxes	(12,199)	(9,981)			(12,199)	(9,981)
Provision for income taxes	(23)	(5)			(23)	(5)
Net loss	$ (12,222)	$ (9,986)	$	$	$ (12,222)	$ (9,986)
Net loss per share, basic and diluted	$ (0.93)	$ (1.28)	$ 0.00	$ 0.00	$ (0.93)	$ (1.28)
Weighted average number of shares outstanding	13,076	7,830	13,076	7,830	13,076	7,830
Condensed consolidated statements of comprehensive loss three and six months ended June 30, 2011 and 2010						
Net loss	$ (12,222)	$ (9,986)	$	$	$ (12,222)	$ (9,986)
Foreign currency translation adjustment	(64)	(35)			(64)	(35)
Comprehensive loss	$ (12,286)	$ (10,021)			$ (12,286)	$ (10,021)

Table of Contents

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

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements and notes included in Item 1 of this Quarterly Report for the six months ended June 30, 2011, as well as the audited financial statements and notes and Management s Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2010, included in our Annual Report on Form 10-K dated March 11, 2011. This Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as we expect, anticipate, target, project, believe, goals, estimate, potential, may, will, expect, might, could, intend, variations of these terms or the negative of those terms and similar expressions are intended to ide these forward-looking statements. Readers are cautioned that these forward-looking statements are 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 I of our Annual Report on Form 10-K for the year ended December 31, 2010 and any risk factors described under the heading Risk Factors in Item 1A of Part II of this Quarterly Report. We do not intend to update these forward looking statements to reflect future events or circumstances.

Overview

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

We are a molecular diagnostics company focused on developing and commercializing our proprietary eSensor detection technology. Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of up to 72 distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the FDA and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and self-contained, disposable test cartridges. Within 30 minutes of receipt of an amplified DNA sample, our XT-8 system produces clear and accurate results. Our XT-8 system supports between one and three analyzers. Each analyzer holds up to eight independent test cartridges, resulting in the XT-8 system supporting up to 24 test cartridges, each of which can be run independently, resulting in a convenient and flexible workflow for our target customers, which are hospitals and reference laboratories. As of June 30, 2011, we had an installed base of 119 analyzers, or placements, with our customers.

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

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

9

Table of Contents

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

Since inception, we have incurred net losses from continuing operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses attributable to continuing operations for the six months ended June 30, 2011 and 2010 were approximately $12.2 million and $10.0 million, respectively. As of June 30, 2011, we had an accumulated deficit of $156.7 million. Our operations to date have been funded principally through sales of capital stock and sales of our previous businesses. We expect to incur increasing expenses over the next several years, principally to develop additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

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

Revenue

	June 30,			
	2011	**2010**	**$ Change**	**% Change**
Three months ended	$ 901	$ 665	$ 236	35%

The increase in revenue for the three month period ended June 30, 2011 as compared to the three month period ended June 30, 2010 was due to a $426,000 increase in reagent revenue driven by the increase in number of our installed base of systems as well as an expanded menu of tests available for sale, including products at higher price points than legacy tests, offset by lower instrument sales of $92,000 and lower licensing revenues of $81,000 for the period.

Cost of Sales and Gross Loss

	June 30,			
	2011	**2010**	**$ Change**	**% Change**
Cost of Sales-three months ended	$ 1,294	$ 749	$ 545	73%
Gross Loss-three months ended	$ 393	$ 84	$ 309	368%

The increase in cost of sales for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 was due to $202,000 in increased expenses related directly to the increase in reagent sales and $120,000 in higher depreciation expense on our rental systems due to increased placements. Additional costs were also incurred in relocating our manufacturing facilities from Pasadena to our Carlsbad location in 2011, including $296,000 in higher payroll, benefits and temporary labor costs. These increases were offset by a decrease of $133,000 in facility-related charges. The increase in gross loss resulted primarily from costs associated with our expanded product offerings which will be reduced as a percentage of sales as our sales volume increases, and the expense of relocating our manufacturing facility which was completed in June 2011.

Operating Expenses

Sales and Marketing

	June 30,			
	2011	**2010**	**$ Change**	**% Change**
Three months ended	$ 1,220	$ 1,285	$ (65)	(5)%

Increases in sales commissions of $98,000 and sample costs for prospective customers of $38,000 were offset by a reduction in product re-branding and website development costs of $101,000 and temporary labor costs of $42,000 for the three months ended June 30, 2011 compared to the three months ended June 30, 2010.

10

Table of Contents

General and Administrative

	June 30,			
	2011	2010	$ Change	% Change
Three months ended	$ 1,810	$ 2,015	$ (205)	(10)%

General and administrative expense decreased for the three months ended June 30, 2011 compared to the three months ended June 30, 2010 due to lower costs related to relocating our UK operations of $121,000, lower associated facility-related costs of $162,000, dues and subscriptions of $93,000 and decreased personnel costs of $113,000, which was offset by an increase in $283,000 in related consulting expense.

Research and Development

	June 30,			
	2011	2010	$ Change	% Change
Three months ended	$ 2,292	$ 1,757	$ 535	30%

The increase in research and development expense for the three months ended June 30, 2011 as compared to the same period in 2010 was due to higher clinical trial costs of $487,000 and prototype materials of $280,000 related to our HCV and RVP clinical trials. These increases were offset by a decrease in relocation expense of $209,000 and decreased lab supplies expense of $101,000.

Other Income, Net

	June 30,			
	2011	2010	$ Change	% Change
Three months ended	$ 147	$ 4	$ 143	3575%

Other income (expense) represent non-operating revenue and expenses, earnings on cash and cash equivalents, interest expense on our loan payable and foreign currency gains or losses. The increase in other income for the three months ended June 30, 2011 as compared to the same period in 2010 was due primarily to a recovered collection on a note receivable of $165,000 that had been reserved in prior periods.

Provision for Income Taxes

	June 30,			
	2011	2010	$ Change	% Change
Three months ended	$ 12	$	$ 12	100%

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

Results of Operations Six months ended June 30, 2011 compared to the six months ended June 30, 2010 *(in thousands)*

Revenue

	June 30,			
	2011	2010	$ Change	% Change
Six months ended	$ 1,659	$ 1,075	$ 584	54%

The increase in revenue for the six month period ended June 30, 2011 as compared to the six month period ended June 30, 2010 was primarily due to a $740,000 increase in reagent revenue driven by the increase in number of our installed base of systems as well as an expanded menu of tests available for sale, including products at higher price points than legacy tests, offset by lower instrument sales of $84,000 and lower

licensing revenues of $59,000 for the period.

Table of Contents

Cost of Sales and Gross Loss

	June 30,			
	2011	2010	$ Change	% Change
Cost of Sales-six months ended	$ 2,795	$ 1,249	$ 1,546	124%
Gross Loss-six months ended	$ 1,136	$ 174	$ 962	553%

The increase in cost of sales for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 was due to $434,000 in increased expenses related directly to the increase in reagent sales, $250,000 in increased costs related to warranties, quality control supplies and inventory reserves and $218,000 in higher depreciation expense on our rental systems due to increased placements. Additional costs were also incurred in relocating our manufacturing facilities from Pasadena to our Carlsbad location in 2011, including $633,000 in higher payroll, benefits and temporary labor costs. The increase in gross loss resulted primarily from costs associated with our expanded product offerings which will be reduced as a percentage of sales as our sales volume increases, and the one-time expense of relocating our manufacturing facility which was completed in June 2011.

Operating Expenses

Sales and Marketing

	June 30,			
	2011	2010	$ Change	% Change
Six months ended	$ 2,439	$ 2,394	$ 45	2%

Increases in sample costs for prospective customers of $230,000 were offset by lower costs related to product re-branding and website development of $183,000 for the six months ended June 30, 2011 compared to the six months ended June 30, 2010.

General and Administrative

	June 30,			
	2011	2010	$ Change	% Change
Six months ended	$ 3,933	$ 4,195	$ (262)	(6)%

General and administrative expense decreased for the six months ended June 30, 2011 compared to the six months ended June 30, 2010 due to lower costs related to relocating our UK operations of $121,000, lower facility-related costs of $527,000 and $349,000 in lower Pasadena related exit costs, offset by increases of $691,000 in consulting costs and $345,000 in fees for professional services.

Research and Development

	June 30,			
	2011	2010	$ Change	% Change
Six months ended	$ 4,856	$ 3,226	$ 1,630	51%

The increase in research and development expense for the six months ended June 30, 2011 was due to higher clinical trial costs, including materials and consulting costs of $1,294,000 related to our HCV and RVP clinical trials and FDA certification of our new Carlsbad manufacturing facility and $244,000 of increased personnel costs. Also, increased reorganization expenses of $224,000 and $217,000 of higher intellectual property-related costs related to new product offerings were offset by reductions in spending for lab supplies of $242,000 and relocation expense of $151,000 as compared to the same period in 2010.

Table of Contents

Other Income, Net

	June 30, 2011	2010	$ Change	% Change
Six months ended	$ 165	$ 8	$ 157	1963%

Other income (expense) represent non-operating income and expenses, earnings on cash and cash equivalents, interest expense on our loan payable and foreign currency gains or losses. The increase in other income for the three months ended June 30, 2011 as compared to the same period in 2010 was due primarily to a recovered collection on a note receivable of $165,000 that had been reserved in prior periods.

Provision for Income Taxes

	June 30, 2011	2010	$ Change	% Change
Six months ended	$ 23	$ 5	$ 18	360%

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

Liquidity and Capital Resources

To date we have funded our operations primarily from the sale of our common stock, borrowings and revenues. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At June 30, 2011, we had $40.1 million of working capital, including $43.5 million in cash and cash equivalents.

Cash Flows

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

	June 30, 2011	2010
Six months ended:		
Cash used by operating activities	$ (7,993)	$ (9,109)
Cash used by investing activities	(974)	(575)
Cash provided by financing activities	34,155	22,852
Effect of foreign exchange rate changes		(47)
Increase in cash and cash equivalents	$ 25,188	$ 13,121

Cash flows used by operating activities

Net cash used in operating activities decreased $1.1 million to $8.0 million for the six months ended June 30, 2011 compared to $9.1 million for the six months ended June 30, 2010. The decreased use of cash was due primarily to collection of a $1.6 million therapeutic tax credit and higher accounts payable and accrued liabilities in the current year, partially offset by the increased net loss for the six months ended June 30,2011.

Cash flows used by investing activities

Net cash used in investing activities increased $399,000 to $974,000 for the six months ended June 30, 2011 compared to $575,000 for the six months ended June 30, 2010 primarily due to increased purchases of our XT-8 systems used for customer rentals which are included in property and equipment and a payment made for intellectual property licensing in 2011.

Cash flows provided by financing activities

Net cash provided by financing activities increased by $11.3 million for the six months ended June 30, 2011 compared to the six months ended June 30, 2010. Cash provided in 2011 resulted from net proceeds of our secondary public offering and a $2.0 million loan payable drawn in March 2011 to finance equipment purchases and tenant improvements in 2010. Cash provided in 2010 resulted substantially from the net proceeds of our initial public offering.

Table of Contents

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

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

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

As of June 30, 2011, the Company had no outstanding loans on the line of credit or the 2011 equipment loan and had drawn $2.0 million to finance 2010 equipment purchases and tenant improvements to its Carlsbad facility against the original 2010 equipment term loan. The loan bears an interest rate of 6.5%. Interest-only payments at the rate of 6.5% are due monthly from the date of each initial equipment advance until July 12, 2011. Initial equipment advances that are then outstanding shall be payable in 24 equal monthly installments of principal, plus all accrued and unpaid interest, beginning on August 12, 2011 and continuing on the same day of each month thereafter through July 12, 2013.

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

The Company s management has prepared cash flow forecasts which indicate, based on the current cash resources available, the availability of unutilized credit facilities, and our ability to access the equity markets 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 cannot be certain that additional capital will be available when and as needed or that our actual cash requirements will not be greater than anticipated. If we require additional capital at a time when investment in diagnostics companies or in the marketplace in general is limited due to the then prevailing market or other conditions, we may not be able to raise such funds at the time that we desire, on acceptable terms, or at all. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have

Table of Contents

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

Critical Accounting Policies and Estimates

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

Contractual Obligations

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

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

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

Other Off-Balance Sheet Arrangements

We have no other off-balance sheet arrangements except for our unutilized credit facilities with Square 1 Bank that provides a revolving line of credit up to $2.0 million and an unutilized equipment term loan totaling $1.0 million at June 30, 2011.

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.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate

changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 10% adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our interest sensitive financial instruments.

Table of Contents

Foreign Currency Exchange Risks

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

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

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

Remediation of Material Weakness

Unrelated to the discovery of the material weakness, we had previously hired a new Chief Executive Officer, Chief Financial Officer and controller to lead our finance our accounting departments. Each of these individuals understands our system of internal controls, including our post-closing procedures which are designed to ensure our financial statements are prepared in accordance with generally accepted accounting principles. These new hires have also provided proper guidance and training on our internal control procedures to other finance and accounting personnel, many of which are also new hires. As a result, we have enhanced communication among our finance and accounting personnel and the personnel from our other departments. We believe these new hires will remediate the material weakness and that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods

presented. No material weakness will be considered remediated, however, until any remedial procedures that we take have operated for an appropriate period, have been tested and management has concluded that they are operating effectively. In addition, we reviewed our processes and procedures for our internal control over financial reporting and we did not identify any additional controls with similar deficiencies. We have reviewed our assessment of the material weakness and our remediation and the status of its implementation and effectiveness with our audit committee.

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

Table of Contents

Changes in Internal Control over Financial Reporting

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

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

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

Table of Contents

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below and all of the other information set forth in this Quarterly Report on Form 10-Q, including our 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 FDA clearance for our first generation molecular diagnostic system in 2006, and commenced a limited marketing effort for this system. We commenced offering our XT-8 system and our Warfarin Sensitivity Test in July 2008. We commenced offering our Cystic Fibrosis Genotyping Test in July 2009 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 $12.2 million for the six months ended June 30, 2011, $18.4 million for the twelve months ended December 31, 2010, $20.0 million in 2009 and $28.4 million in 2008. At June 30, 2011, we had an accumulated deficit of approximately $156.7 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 cannot 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 will need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all. If additional capital is not available, we may have to curtail or cease operations.

Until such time, if ever, as we can generate substantial product revenues, we will be required to finance our operations with our cash resources. We will need to raise additional funds in the future to support our operations. We cannot be certain that additional capital will be available as needed or on acceptable terms, or at all. If we require additional capital at a time when investment in our company, in molecular diagnostics companies or the marketplace in general is limited, we may not be able to raise such funds at the time that we desire, or at all. If we do raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be significantly diluted 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, and products or grant licenses on terms that are not favorable to us.

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

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

If we experience a material defect or error, this could result in loss or delay of revenues, increased costs to produce our tests, delayed market acceptance, damaged reputation, diversion of development and management resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could materially harm our business, financial condition and results of operations.

Table of Contents

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

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

We currently market three FDA-cleared diagnostic tests and have developed one other diagnostic test currently labeled for IUO. In addition, we have several 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 cannot 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 significantly impaired.

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

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

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

the costs associated with being a public company.

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

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

The markets for our technologies and products are very competitive, and we expect the intensity of competition to increase. We compete with many companies in the United States engaged in the development, commercialization

Table of Contents

and distribution of similar products intended for clinical molecular diagnostic applications. Categories of competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, including Luminex Corporation; Nanosphere; Qiagen NV; Abbott Diagnostics; Hologic, Inc. and Innogenetics Inc.;
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods including Quest Diagnostics and Laboratory Corporation of America; and
- companies that manufacture laboratory-based tests and analyzers including Cephid; Gen-Probe, Inc.; Siemens; Hologic, Inc.; Qiagen NV; Roche Diagnostics; and Abbott Diagnostics.

Our diagnostic tests also face competition with the laboratory-developed-tests, or LDTs, developed by national and regional reference laboratories and hospitals. Such laboratory-developed tests may not be subject to the same requirements for clinical trials and FDA submission requirements that may apply to our products.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and our competitors improve their current products and expand their menu of diagnostic tests. Many of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. The impact of these factors may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue.

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

We have primarily placed our XT-8 systems with customers at no initial charge through placement agreements, under which customers commit to purchasing minimum quantities of test cartridges over a period of one to three years, with a component of the reagent cartridge price allocated to recover the instrument cost. While we also offer our XT-8 systems for sale, we have sold only 13 of our systems. We expect sales of our diagnostic tests associated with our XT-8 system will account for the vast majority of our revenues for at least the next several years. We intend to dedicate a significant portion of our resources to the commercialization of our XT-8 system and our existing FDA-cleared diagnostic tests. Although we intend to develop a broad range of additional diagnostic tests for use with the XT-8 system and our NexGen system, we cannot assure you when or if we will obtain FDA clearance for the tests we develop in the future, or whether the market will accept such new products. As a result, to the extent that our XT-8 system and our existing and future FDA-cleared diagnostic tests are not commercially successful or are withdrawn from the market for any reason, our revenues will be harmed and our business, operating results and financial condition will be harmed.

We may not be successful in developing our NexGen system.

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

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.

Medical offices and many hospitals outsource their molecular diagnostic testing needs to national or regional reference laboratories. Our business success depends on our ability to convince these target laboratories and

Table of Contents

hospitals to replace their current testing platforms and/or send-out tests, with our XT-8 system and related diagnostic tests. We must also continue to increase the number of available tests, and test sell-through, on our installed systems.

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

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

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

We must manufacture, or engage third parties to manufacture, components of our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on inventory levels, current market trends and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our products, there could be significant differences between our estimates and the actual amounts of products we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

We currently manufacture our proprietary test cartridges at our Carlsbad, California manufacturing facility. We outsource manufacturing of our XT-8 system and much of the disposable component molding and component assembly for our test cartridges. 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. While we work closely with Aubrey Group Inc. to try to ensure continuity of supply while maintaining high quality and reliability, we cannot guarantee that these efforts will be successful. Should Aubrey Group Inc. become unable or unwilling to continue to meet our supply needs, we may experience delays in qualifying a new source or may not obtain as favorable pricing or other terms, any of which could harm our business, financial condition or results of operation. In addition, our 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.

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

The manufacturing operations for our test cartridges 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.

Table of Contents

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

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

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

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

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

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

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

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

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

If we execute our 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;

competition from companies located in the countries in which we offer our products, which may be a competitive disadvantage;

Table of Contents

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

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

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

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

We have limited marketing, sales and distribution experience and capabilities. 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. We are currently in varying stages of development of 4 additional tests:

- Respiratory Viral Panel: A qualitative nucleic acid multiplex test designed for the simultaneous detection and identification of multiple respiratory virus nucleic acids and mutations;
- Plavix Sensitivity: For the multiplexed detection and genotyping of the *2, *3, *4, *5, *6, *7, *8, *9, *10, *13 and *17 alleles of the cytochrome P450 (CYP450) 2C19 gene locus;
- Kras-Mutation: Designed for the multiplexed detection and genotyping of 12 mutations in codons 12 and 13 of KRAS and the V600E mutation in BRAF; and
- Hepatitis C Virus Genotyping: Designed to detect and subtype the different genotypes for the Hepatitis C Virus (HCV).

As of June 30, 2011, we had 119 analyzers installed with customers. Our ability to achieve profitability depends on attracting customers for the XT-8 system, expanding the number of tests we offer, and building brand loyalty. To successfully perform sales, marketing, distribution and

customer support functions ourselves, we face a number of risks, including:

- our ability to attract and retain the skilled support team, marketing staff and sales force necessary to commercialize and gain market acceptance for our technology and our products;
- the ability of our sales and marketing team to identify and penetrate the potential customer base, including hospitals, national and regional reference laboratories; and
- the difficulty of establishing brand recognition and loyalty for our products.

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

Table of Contents

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

The majority of our XT-8 systems are sold to customers via reagent rental agreements, under which customers obtain the XT-8 System in return for a commitment to purchase minimum quantities of test cartridges over a period of one to three years. Accordingly, we must incur the expense of manufacturing XT-8 Systems well in advance of receiving sufficient revenues from test cartridges to recover our manufacturing expenses. We also offer our XT-8 systems for sale. In 2010, we sold ten XT-8 systems to customers which included the sale of twelve analyzers. 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 use hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research, product development and manufacturing processes involve the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research, development and production efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

Our corporate structure may create tax inefficiencies.

As a result of our reorganization in 2010 and prior to the reorganization steps that took place in June 2011, Osmetech was a wholly-owned subsidiary of GenMark and a controlled foreign corporation for U.S. federal income tax purposes. This organizational structure may have created inefficiencies, as certain types of income and investments of Osmetech that otherwise would not be currently taxable under general tax rules, may have become taxable. In addition, conveyance of intellectual property rights from one subsidiary to another could create taxable income. Distributions from GenMark to its operating subsidiaries or amongst the U.S. operating subsidiaries of GenMark could have been subject to additional U.S. and foreign income tax withholding and result in lower profits. In June 2011, the Company took steps to reorganize and streamline its corporate structure. As a result of these steps, all operations will be included in a U.S. federal consolidated tax return and many of the inefficiencies described above are eliminated on a go-forward basis.

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

As of December 31, 2010, we had net operating loss carryforwards of approximately $77.9 million for U.S. federal income tax purposes. These loss carryforwards will expire in varying amounts through 2030. 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. In addition, our ability to use the current net operating loss carryforwards might be further limited by the issuance of common stock in the future. 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.

Table of Contents

We have determined that we have experienced multiple ownership changes under Section 382. We have estimated that approximately $24.7 million of federal net operating losses may be utilized in the future based on limitations that we have calculated under Section 382. We are currently analyzing alternative positions and additional factual information that may increase the amount of net operating losses that could subsequently be utilized. To the extent that this additional information becomes available and could increase net operating losses available for use, we will adjust our deferred tax assets accordingly, with a corresponding adjustment to our valuation allowance. We also had non-U.S. net operating loss carryforwards of approximately $30.4 million as of December 31, 2010.

Risks Related to Regulation

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

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

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

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

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

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

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

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

Table of Contents

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 cannot guarantee that any of our tests are or will be covered by the CPT codes that we believe may be applied to them or that any of our tests or other products will be approved for coverage or reimbursement by Medicare 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, such as ours, 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 harm 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 harm the demand for and reimbursement available for our products, which in turn, could harm pricing and sales. If our customers are not adequately reimbursed for our products, they may reduce or discontinue purchases of our products, which would cause our revenues to decline.

We 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 announced and/or unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies.

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

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

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

the FDA s refusal to grant pending future clearance or pre-market approval for our products;

withdrawal or suspension of marketing clearances or approvals;

clinical holds;

warning letters;

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

criminal prosecution.

Table of Contents

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

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

The use of our diagnostic products by our customers is also affected by the Clinical Laboratory Improvement Amendments 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.

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 510(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 harm our business, financial condition and results of operations.

Federal and state governments in the United States are also undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted 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 tax liabilities and costs, which could adversely affect our business and financial condition.

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, or 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.

Table of Contents

Our commercial, research, and other financial relationships with healthcare providers and institutions are subject to various federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the knowing offer, receipt or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The federal False Claims Act, or the FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. 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 harm on our business, financial condition 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 harm our business.

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

Risks Related to Our Intellectual Property

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;

- a court prohibiting us from selling or licensing our product unless the third party licenses its product rights to us, which it is not required to do;

if a license is available from a third party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Table of Contents

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

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

From time to time we may become engaged in litigation with third parties having patent or other intellectual property rights alleging that our products or proprietary technologies infringe their intellectual property rights. These third parties and others who may in the future threaten us with such litigation, are or may be better capitalized and have more resources than us. In addition, in order to commercialize certain new or existing tests 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 properly rights. We have received correspondence bringing to our attention certain patent rights held by third parties and offering to discuss licensing terms to the patents. Some of these letters relate to patents that are important to our products. Independently, we have also identified patents held by third parties that cover one or more of our products or planned products. Although we have taken licenses to numerous such third-party patents, we have also declined to license certain patents in instances where we do not believe our existing products infringe valid claims.

In May 2010, we received correspondence from Caliper Life Sciences, Inc., or Caliper, alleging that we infringe certain microfluidic patents held by Caliper relating to fluid handling technologies that we utilize in the cartridges used in all of our tests and demanding that we take a license to its patents or else Caliper would institute litigation against us. On November 10, 2010, we filed a complaint for declaratory judgment against Caliper in the United States District Court for the Northern District of California. In our complaint, we requested a declaration from the court that certain of Caliper s microfluidic patents were invalid, and that we did not infringe on these patents. On February 24, 2011, we entered into an agreement with Caliper pursuant to which we agreed to dismiss our action for declaratory judgment, without prejudice, and Caliper agreed not to assert infringement by us on these patents for a period of six months. Following the expiration of this six-month period, Caliper may again assert that we are infringing its patents and that we are required to take a license to its patents and could institute legal action. If one of Caliper s patents or any other third-party patents were found to be valid and cover any of our products, proprietary technologies, including our fluid handling technologies used in our test cartridges, or their uses, we or any collaborator could be enjoined from using or selling our products by a court and/or 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, using our fluid handling technologies used in our test cartridges or other core technologies or developing new tests. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief that 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 can be extremely costly and could significantly affect our results of operations and divert the attention of managerial and technical personnel.

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 100 issued U.S. patents, 50 issued foreign patents and 28 pending domestic and foreign patent applications, all of which we own directly or for which we are the exclusive licensee and that expire between 2013 and 2028. 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

Table of Contents

not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

We have also licensed certain intellectual property from third parties related to our products, and we rely on them to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents.

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. In addition, Congress is 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.

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

Table of Contents

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

changes in market valuations or earnings of our competitors;

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

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

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

changes in legislation or regulatory policies, practices or actions;

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

recruitment or departure of key personnel;

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

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

the trading volume of our common stock.

In addition, the stock market in general, the NASDAQ Global Market and the market for diagnostics companies in particular may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of

Table of Contents

our business, our financial condition or results of operations. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class-action litigation. Class-action litigation, even if unsuccessful, could be costly to defend and divert management s attention and resources, which could further materially harm our financial condition and results of operations.

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

As of June 30, 2011, we had 20,474,570 shares of our common stock outstanding. Sales of a number shares of common stock in the public market, or the expectation of such sales, could cause the market price of our common stock to decline. In addition, our 2010 Plan provides for annual increases in the number of shares available for issuance under the plan. We may also sell additional common stock in subsequent public offerings, which may adversely affect the market price of our common stock.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may harm our operating results, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause investors to lose confidence in our operating results and in the accuracy of our financial reports and could harm our business and 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 fiscal year ending December 31, 2011. The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or 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 process 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 for fiscal year 2010 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/or to engage a third party consulting firm to assist in risk assessment, documentation and testing of controls. 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 the NASDAQ Global Market 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 the NASDAQ Global Market and we could lose investor confidence in the accuracy and completeness of our financial reports, which would materially harm our business and the price of our common stock and our ability to access the capital markets.

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

Table of Contents

activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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

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

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

Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of 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.

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

Table of Contents

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

Unregistered Sales of Equity Securities

None

Use of Proceeds from Registered Securities

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

On June 22, 2011, we closed a secondary public offering, in which we sold 8,125,440 shares of common stock at a price of $4.25 per share, which included a public offering of 7,065,600 shares and 1,059,840 purchased by the underwriter in accordance with the exercise of an over-allotment option. The aggregate offering price for shares sold in the offering was $34.5 million. The offer and sale of all of the shares in the public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-174524), which was declared effective by the SEC on June 16, 2011. The offering commenced as of June 20, 2011 and did not terminate before all of the securities registered in the registration statement were sold. Canaccord Genuity acted as sole book-running manager for the offering and William Blair & Company acted as co-lead manager of the offering. There were no selling stockholders in the offering. We raised approximately $31.7 million in net proceeds after deducting underwriting discounts and commissions of $2.2 million and other offering expenses of $0.6 million. 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 secondary public offering as described in our final prospectus filed with the SEC on June 17, 2011 pursuant to Rule 424(b). We invested the funds received in registered money market funds and certificates of deposit.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

Table of Contents

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.

Table of Contents

SIGNATURES

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

GENMARK DIAGNOSTICS, INC.

Date: August 15, 2011

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

Table of Contents

EXHIBIT INDEX

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

31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.
101*	XBRL Instance Document
101*	XBRL Taxonomy Extension Schema Document
101*	XBRL Taxonomy Calculation Linkbase Document
101*	XBRL Taxonomy Label Linkbase Document
101*	XBRL Taxonomy Presentation Linkbase Document

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