

Edgar Filing: GenMark Diagnostics, Inc. - Form 10-Q

GenMark Diagnostics, Inc.
Form 10-Q
May 05, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

or

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

For the transition period from _____ to _____

Commission File Number: 001-34753

GenMark Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

| | |
|--|--------------------------------------|
| Delaware | 27-2053069 |
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

| | |
|--|------------|
| 5964 La Place Court | 92008-8829 |
| Carlsbad, California | |
| (Address of principal executive offices) | (Zip code) |

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

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

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

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

| | |
|--|---|
| Large accelerated filer <input type="checkbox"/> | Accelerated filer <input checked="" type="checkbox"/> |
|--|---|

| | |
|--|--|
| Non-accelerated filer <input type="checkbox"/> | Smaller reporting company <input type="checkbox"/> |
|--|--|

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

The number of outstanding shares of the registrant's common stock on May 1, 2015 was 42,138,925.

GENMARK DIAGNOSTICS, INC.
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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

| | March 31, 2015 | December 31, 2014 |
|--|-------------------|----------------------|
| Current Assets | | |
| Cash and cash equivalents | \$36,913 | \$36,855 |
| Marketable Securities | 34,041 | 33,651 |
| Accounts receivable - net of allowances of \$2,702 and \$2,702, respectively | 4,444 | 4,889 |
| Inventories | 2,148 | 2,137 |
| Prepaid expenses and other current assets | 770 | 575 |
| Total current assets | 78,316 | 78,107 |
| Property and equipment, net | 11,354 | 11,052 |
| Intangible assets, net | 1,806 | 1,870 |
| Restricted cash | 758 | 758 |
| Other long-term assets | 115 | 183 |
| Total assets | \$92,349 | \$91,970 |
| Current liabilities | | |
| Accounts payable | \$3,390 | \$3,468 |
| Accrued compensation | 3,388 | 5,172 |
| Other current liabilities | 2,832 | 3,653 |
| Total current liabilities | 9,610 | 12,293 |
| Long-term liabilities | | |
| Deferred rent | 1,402 | 1,445 |
| Long term debt | 9,502 | — |
| Other non-current liabilities | 249 | 208 |
| Total liabilities | 20,763 | 13,946 |
| Stockholders' equity | | |
| Preferred stock, \$0.0001 par value; 5,000 authorized, none issued | — | — |
| Common stock, \$0.0001 par value; 100,000 authorized; 42,128 and 41,859 shares issued and outstanding as of March 31, 2015 and December 31, 2014, respectively | 4 | 4 |
| Additional paid-in capital | 343,925 | 340,502 |
| Accumulated deficit | (272,341) | (262,472) |
| Accumulated other comprehensive loss | (2) | (10) |
| Total stockholders' equity | 71,586 | 78,024 |
| Total liabilities and stockholders' equity | \$92,349 | \$91,970 |

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share data)

| | Three Months Ended March 31, | |
|---|---------------------------------|-----------|
| | 2015 | 2014 |
| Revenue | | |
| Product revenue | \$10,012 | \$7,866 |
| License and other revenue | 95 | 47 |
| Total revenue | 10,107 | 7,913 |
| Cost of revenue | 3,991 | 3,591 |
| Gross profit | 6,116 | 4,322 |
| Operating expenses | | |
| Sales and marketing | 3,693 | 2,979 |
| General and administrative | 3,671 | 2,933 |
| Research and development | 8,779 | 7,270 |
| Total operating expenses | 16,143 | 13,182 |
| Loss from operations | (10,027) | (8,860) |
| Other income (expense) | | |
| Interest income | 36 | 86 |
| Interest expense | (73) | (1) |
| Other income (expense) | 217 | (2) |
| Total other income (expense) | 180 | 83 |
| Loss before provision for income taxes | (9,847) | (8,777) |
| Provision for income taxes | 22 | 6 |
| Net loss | \$(9,869) | \$(8,783) |
| Net loss per share, basic and diluted | \$(0.24) | \$(0.21) |
| Weighted average number of shares outstanding, basic and diluted | 41,774 | 41,079 |
| Other comprehensive loss | | |
| Net loss | \$(9,869) | \$(8,783) |
| Foreign currency translation adjustments | 9 | — |
| Net unrealized gains (losses) on available-for-sale investments, net of tax | (17) | 12 |
| Comprehensive loss | \$(9,877) | \$(8,771) |

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

| | Three Months Ended March 31, | |
|---|------------------------------|------------|
| | 2015 | 2014 |
| Operating activities | | |
| Net loss | \$(9,869 |) \$(8,783 |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 797 | 574 |
| Amortization of premiums on investments | 73 | 198 |
| Amortization of deferred debt issuance costs | 49 | — |
| Gain on sale of investment in preferred stock | (223 |) — |
| Stock-based compensation | 2,339 | 1,389 |
| Non-cash inventory adjustments | 402 | 219 |
| Other non-cash adjustments | 20 | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 445 | 283 |
| Inventories | (366 |) 169 |
| Prepaid expenses and other assets | (216 |) 107 |
| Accounts payable | (775 |) (449 |
| Accrued compensation | (919 |) 10 |
| Other liabilities | (22 |) (101 |
| Net cash used in operating activities | (8,265 |) (6,384 |
| Investing activities | | |
| Purchase of available-for-sale securities | (14,797 |) (13,039 |
| Payments for intellectual property licenses | (550 |) — |
| Purchases of property and equipment | (411 |) (1,149 |
| Proceeds from sales of marketable securities and preferred stock | 223 | 5,499 |
| Maturities of short-term investments | 14,350 | 7,250 |
| Net cash used in investing activities | (1,185 |) (1,439 |
| Financing activities | | |
| Principal repayment of borrowings | (5 |) (42 |
| Proceeds from borrowings | 10,000 | — |
| Costs associated with debt issuance | (700 |) — |
| Proceeds from stock option exercises | 222 | 25 |
| Net cash provided by (used in) financing activities | 9,517 | (17 |
| Effect of exchange rate changes on cash | (9 |) — |
| Net decrease in cash and cash equivalents | 58 | (7,840 |
| Cash and cash equivalents at beginning of period | 36,855 | 35,723 |
| Cash and cash equivalents at end of period | \$36,913 | \$27,883 |
| Non-cash investing and financing activities | | |
| Transfer of systems from property and equipment into inventory | \$48 | \$54 |
| Property and equipment costs incurred but not paid included in accounts payable | \$818 | \$1,022 |
| Supplemental cash flow disclosures | | |
| Cash paid for income taxes, net | \$17 | \$8 |
| Cash received for interest | \$109 | \$284 |
| Cash paid for interest | \$73 | \$1 |

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

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

As the reorganization was deemed to be a transaction under common control, GenMark accounted for the reorganization in a manner similar to a pooling-of-interests. Once the reorganization became effective, all stock options granted under the Osmetech plc 2003 U.S. Equity Compensation Plan, long term incentive awards and all warrants issued by Osmetech were exchanged for options and warrants exercisable for common stock of the Company.

Basis of Presentation

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses from operations since its inception and had an accumulated deficit of \$272,341,000 as of March 31, 2015. Management expects operating losses to continue for the foreseeable future. The Company's ability to transition to profitable operations is dependent upon achieving a level of revenues adequate to support its cost structure through expanding its product offerings and consequently increasing its product revenues. Cash, cash equivalents and marketable securities as of March 31, 2015 were \$71,712,000. The Company has prepared cash flow forecasts which indicate, based on the Company's current cash resources available, that the Company will have sufficient resources to fund its business for at least the next 12 months.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP, and applicable regulations of the U.S. Securities and Exchange Commission, or the SEC, and should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on February 24, 2015. These unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary for a fair statement of the results for the interim periods presented. These adjustments are of a normal, recurring nature. Interim period operating results may not be indicative of the operating results for the full year or any future period.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the notes thereto. The Company's significant estimates included in the preparation of the financial statements are related to accounts receivable, inventories, property and equipment, intangible assets, employee-related compensation accruals, warranty liabilities, tax valuation accounts and share-based compensation. Actual results could differ from those estimates.

Segment Information

The Company currently operates in one reportable business segment, which encompasses the development, manufacturing, sales and support of instruments and molecular tests based on its proprietary eSensor® detection technology. Substantially all of the Company's operations and assets are in the United States of America.

Reclassifications

Costs previously reported as cost of revenue totaling \$119,000 in the three months ended March 31, 2014 have been reclassified as general and administrative expenses to better align those costs with the functional areas that benefit from those expenditures. In addition, the Company also reclassified \$198,000 included in other income and expense in 2014 into interest income to better align the true nature of the expenses. Reclassifications of prior year financial information have been made to conform to the current year

presentation. None of the changes impacts the Company's previously reported consolidated net revenue, earnings from operations, net earnings or net earnings per share.

Recent Accounting Pronouncements

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

In April 2015, the FASB issued Accounting Standards Update (ASU) 2015-03, Interest - Imputation of Interest. The standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the debt liability. The Company has retrospectively adopted this standard. The debt issuance costs have been recognized as a direct reduction to short and long term debt liability in the Condensed Consolidated Balance Sheets for all periods presented.

In May 2014, the FASB issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers. The new standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 will be effective for the Company beginning in the first quarter of fiscal 2018 and allows for a full retrospective or a modified retrospective adoption approach. The Company is currently evaluating the impact of ASU 2014-09 on its consolidated financial statements.

Cash and Cash Equivalents and Marketable Securities

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

Restricted Cash

Restricted cash represents amounts designated for uses other than current operations and included \$758,000 at March 31, 2015 held as security for the Company's letter of credit with Banc of California.

Receivables

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

Product Warranties

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

Intangible Assets

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

Impairment of Long-Lived Assets

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

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and include direct labor, materials, and manufacturing overhead. The Company periodically reviews inventory for evidence of slow-moving or obsolete parts, and writes inventory down to market value, as needed. This write down is based on management's review of inventories on hand, compared to estimated future usage and sales, shelf-life assumptions, and assumptions about the likelihood of obsolescence. If actual market conditions are less favorable than those projected by the Company, additional inventory write-downs may be required. Inventory impairment charges establish a new cost basis for inventory and charges are not reversed subsequently to income, even if circumstances later suggest that increased carrying amounts are recoverable.

Property and Equipment, net

Property, equipment and leasehold improvements are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which are identified below. Repair and maintenance costs are expensed as incurred.

| | |
|------------------------------------|--|
| Machinery and laboratory equipment | 3 - 5 years |
| Instruments | 4 years |
| Office equipment | 5 years |
| Leasehold improvements | over the shorter of the remaining life of the lease or the useful economic life of the asset |

Income Taxes

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

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

2. Stock-Based Compensation

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

function.

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

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Expected Term. Expected term represents the period that the stock-based awards are expected to be outstanding and is determined by using the simplified method.

Expected Volatility. Expected volatility represents the volatility in the Company's estimated stock price over the expected term of the stock option and is determined by review of the Company's and similar companies' historical experience.

Expected Dividend. The Black-Scholes Option Pricing Model calls for a single expected dividend yield as an input. The Company assumed no dividends as it has never paid dividends and has no current plans to do so.

Risk-Free Interest Rate. The risk-free interest rate used in the Black-Scholes Option Pricing Model is based on published U.S. Treasury rates in effect at the time of grant for periods corresponding with the expected term of the option.

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

Employee participation in the Company's 2010 Equity Incentive Plan, or the 2010 Plan, is at the discretion of the Compensation Committee of the Board of Directors of the Company. All stock options granted under the 2010 Plan are exercisable at a per share price equal to the closing quoted market price of a share of the Company's stock on the NASDAQ Global Market on the grant date and generally vest over a period of between one and four years.

Stock options are generally exercisable for a period of up to 10 years after grant and are typically forfeited if employment is terminated before the options vest. As of March 31, 2015, there were 282,659 shares available for future grant under the 2010 Plan. Each grant of stock options, restricted stock awards, restricted stock units and market-based stock units reduces the number of shares available for grant under the 2010 Plan.

The following table summarizes stock option activity during the three months ended March 31, 2015:

| | Number of Shares | Weighted Average Exercise Price |
|---|---------------------|---------------------------------------|
| Outstanding at December 31, 2014 | 2,479,435 | \$8.66 |
| Granted | 747,950 | \$13.17 |
| Exercised | (43,846) | \$4.99 |
| Cancelled | (9,808) | \$11.46 |
| Outstanding at March 31, 2015 | 3,173,731 | \$9.77 |
| Vested and expected to vest at March 31, 2015 | 2,801,937 | \$7.06 |
| Exercisable at March 31, 2015 | 1,486,655 | \$7.06 |

The weighted average fair value of stock options granted during the three months ended March 31, 2015 was \$6.44. Options that were exercisable as of March 31, 2015 had a remaining weighted average contractual term of 6.09 years, and an aggregate intrinsic value of \$8,844,383. As of March 31, 2015, there were 3,173,731 stock options outstanding, which had a remaining weighted average contractual term of 7.75 years and an aggregate intrinsic value of \$10,419,803.

Valuation of Stock-Based Awards

The assumptions used in the valuation of stock-based awards for the periods ended March 31, 2015 and 2014 are summarized in the following table:

| | Three Months Ended March 31, | | | |
|-----------------------------|---------------------------------|---|------|---|
| | 2015 | | 2014 | |
| Expected volatility (%) | 50 | % | 70 | % |
| Expected life (years) | 6.08 | | 6.08 | |
| Risk free interest rate (%) | 1.69 | % | 1.82 | % |
| Expected dividend yield (%) | 0 | % | 0 | % |

In March 2013, the Company transitioned to granting restricted stock units under the 2010 Plan in lieu of granting restricted stock awards. The Company's restricted stock award and restricted stock unit activity for the three months ended March 31, 2015 was as follows:

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| | Restricted Stock Awards | | Restricted Stock Units | |
|-------------------------------|-------------------------|---|------------------------|---|
| | Number of Shares | Weighted Average Grant Date Fair Value | Number of Shares | Weighted Average Grant Date Fair Value |
| Unvested at December 31, 2014 | 173,610 | \$4.56 | 741,992 | \$11.46 |
| Granted | — | \$— | 522,396 | \$13.17 |
| Vested | (43,389) | \$4.34 | (213,855) | \$11.86 |
| Canceled or expired | (312) | \$5.96 | (4,868) | \$12.10 |
| Unvested at March 31, 2015 | 129,909 | \$4.63 | 1,045,665 | \$12.23 |

As of March 31, 2015, there was \$511,993 of unrecognized compensation cost related to outstanding restricted stock awards, which is expected to be recognized over a weighted average period of 1.07 years. The total fair value of restricted stock awards that vested during the three months ended March 31, 2015 and 2014 was \$561,256 and \$1,746,771, respectively.

As of March 31, 2015, there was \$9,227,860 of unrecognized compensation cost related to restricted stock units, which is expected to be recognized over a weighted average period of 3.18 years. The total fair value of restricted stock units that vested during the three months ended March 31, 2015 and 2014 was \$2,708,096 and \$726,430, respectively.

Restricted stock awards or units may be granted at the discretion of the Compensation Committee of the Board of Directors under the 2010 Plan in connection with the hiring or retention of personnel and are subject to certain conditions. Restrictions expire at certain dates in accordance with specific provisions in the applicable award agreement. During the three months ended March 31, 2015 and 2014, stock-based compensation expense for restricted stock units and awards was \$1,103,952 and \$911,119, respectively.

The Company issued 154,929 market-based restricted stock units in February 2015 which contain provisions to earn up to 200% of the target number of units. The fair value of market stock units was estimated on the date of grant using the Monte Carlo Simulation Valuation Model, which estimates the potential outcome of reaching the market condition based on simulated future stock prices, with the following assumptions: expected volatility of 44.7% and risk free interest rate of 1.1%. The vesting and issuance of Company stock depends on the Company's stock performance as compared to the Nasdaq Composite Index. The awards vest in three installments on December 31, 2015, December 31, 2016 and December 31, 2017 if stock performance metrics are achieved. At March 31, 2015, there was \$2,626,984 of unrecognized stock-based compensation expense related to these awards, which is expected to be recognized over a weighted average period of 2.76 years. During the three months ended March 31, 2015 and 2014, stock-based compensation expense for market-based units was \$172,585 and \$0, respectively.

The Company issued 43,200 performance-based restricted stock units in March 2014 with a grant date fair value of \$12.30. The vesting and issuance of Company stock pursuant to these awards depends on obtaining regulatory clearance of various products within a defined time. Stock-based compensation expense for these performance-based awards is recognized when it is probable that the applicable performance criteria will be satisfied. The probability of achieving the relevant performance criteria is evaluated on a quarterly basis. At March 31, 2015, there was \$398,520 of unrecognized stock-based compensation expense related to these awards.

Employee Stock Purchase Plan

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

The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors; provided that no offering period may exceed 27 months. Employees may invest up to 10% of their gross compensation through payroll

deductions. In no event may an employee purchase more than 1,500 shares of common stock during any six-month offering period. As of March 31, 2015, there were 528,142 shares of common stock available for issuance under the ESPP. Stock-based compensation expense related to the ESPP which is calculated using the Black-Scholes model at the beginning of each six-month offering period has been recorded during the three months ended March 31, 2015.

3. Net Loss per Common Share

Basic net loss per share is calculated by dividing loss available to stockholders of the Company's common stock (the numerator) by the weighted average number of shares of the Company's common stock outstanding during the period (the denominator). Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding.

Diluted loss per share is calculated in a similar way to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the dilutive potential shares had been issued, unless the effect would be anti-dilutive.

The computations of diluted net loss per share for the three months ended March 31, 2015 and 2014 did not include the effects of the following stock options and restricted stock awards which were outstanding as of the end of each period because the inclusion of these securities would have been anti-dilutive (in thousands).

| | Three Months Ended March 31, | |
|--|------------------------------|-------|
| | 2015 | 2014 |
| Options outstanding to purchase common stock | 3,174 | 2,593 |
| Unvested restricted stock | 1,363 | 1,127 |
| Total | 4,537 | 3,720 |

4. Inventories

Inventory on hand as of March 31, 2015 and December 31, 2014 was comprised of the following (in thousands):

| | March 31, 2015 | December 31, 2014 |
|-----------------|----------------|-------------------|
| Raw materials | \$783 | \$593 |
| Work-in-process | 919 | 660 |
| Finished goods | 446 | 884 |
| | \$2,148 | \$2,137 |

5. Property and Equipment, net

Property and equipment comprised the following as of March 31, 2015 and December 31, 2014 (in thousands):

| | March 31, 2015 | December 31, 2014 |
|--------------------------------------|----------------|-------------------|
| Property and equipment—at cost: | | |
| Plant and machinery | \$7,815 | \$6,737 |
| Instruments | 6,366 | 6,611 |
| Office equipment | 1,478 | 1,441 |
| Leasehold improvements | 4,084 | 4,050 |
| Total property and equipment—at cost | 19,743 | 18,839 |
| Less accumulated depreciation | (8,389) | (7,787) |
| Property and equipment, net | \$11,354 | \$11,052 |

Depreciation expense was \$733,000 and \$516,000 for the three months ended March 31, 2015 and 2014, respectively.

6. Intangible Assets, net

Intangible assets as of March 31, 2015 and December 31, 2014 were as follows (in thousands):

| | March 31, 2015 | | | December 31, 2014 | | |
|--------------------------------|-----------------------|--------------------------|---------------------|-----------------------|--------------------------|---------------------|
| | Gross carrying amount | Accumulated amortization | Net carrying amount | Gross carrying amount | Accumulated amortization | Net carrying amount |
| Licensed intellectual property | \$2,750 | (944) | \$1,806 | \$2,750 | (880) | \$1,870 |

Intellectual property licenses have a weighted average remaining amortization period of 7.12 years as of March 31, 2015. Amortization expense for intangible assets for the three months ended March 31, 2015 and 2014 was \$64,000 and \$58,000, respectively. Estimated future amortization expense for these licenses (assuming no impairment charges) is as follows (in thousands):

| Fiscal Years Ending | Future Amortization Expense |
|---------------------|-----------------------------|
| Remaining in 2015 | \$ 193 |
| 2016 | 254 |
| 2017 | 254 |
| 2018 | 254 |
| 2019 | 254 |
| Thereafter | 597 |
| Total | \$ 1,806 |

7. Loan Payable

Long term debt consisted of the following (in thousands):

| | March 31, 2015 | December 31, 2014 |
|--|----------------|-------------------|
| Term Loan A | | |
| 6.9% Principal | \$10,000 | \$— |
| Unamortized issuance discount | (704) |) — |
| Total Debt, net | 9,296 | — |
| Less current portion of long-term debt | 206 | — |
| Long-Term Debt | \$9,502 | \$— |
| Term Loans | | |

In January 2015, the Company entered into a Loan and Security Agreement, or the Agreement, with General Electric Capital Corporation, or GECC, and certain other financial institutions party thereto, as lenders, pursuant to which the Company obtained (a) up to \$35,000,000 in a series of term loans and (b) a revolving loan in the maximum amount of \$5,000,000. Under the terms of the Agreement, the Company may, subject to certain conditions, borrow: \$10,000,000 on or before March 31, 2015 (“Term Loan A”);

- an additional \$10,000,000 (“Term Loan B”), subject to the Company’s satisfaction of regulatory requirements necessary to CE Mark its ePlex™ system in Europe by a specified date; and
- an additional \$15,000,000 (“Term Loan C,” and together with Term Loan A and Term Loan B, the “Term Loans”), subject to the Company’s satisfaction of FDA 510(k) market clearance for the sale of the Company’s ePlex™ system in the United States by a specified date.

On March 27, 2015, the Company borrowed \$10,000,000 pursuant to Term Loan A. The Term Loans will accrue interest at a rate equal to, a) the greater of 1.00% or the 3-year treasury rate in effect at the time of funding, plus (b) an applicable margin between 4.95% and 5.90% per annum. The Company is only required to make interest payments on amounts borrowed pursuant to the Term Loans from the applicable funding date until March 1, 2017 (the “Interest Only Period”). Following the Interest Only Period, monthly installments of principal and interest under the Term Loans will be due until the original principal amount and applicable interest is fully repaid by January 12, 2019 (the “Maturity Date”).

Under the Agreement, the Company is required to comply with certain affirmative and negative covenants, including, without limitation, delivering reports and notices relating to the Company’s financial condition and certain regulatory events and intellectual property matters, as well as limiting the creation of liens, the incurrence of indebtedness, and the making of certain investments,

payments and acquisitions, other than as specifically permitted by the Agreement. As of March 31, 2015, the Company was in compliance with all covenants under the Agreement.

Revolving Loan

Pursuant to the Agreement, the Company may borrow up to \$5,000,000 under the revolving loan facility. Borrowings under the revolving loan will accrue interest at a rate equal to (a) the greater of 1.25% per annum or a base rate as determined by a three-month LIBOR-based formula, plus (b) an applicable margin between 2.95% and 3.95% based on certain criteria as set forth in the Agreement. All principal and interest outstanding under the revolving loan is due and payable on the Maturity Date. Following the funding of Term Loan A, the Company is required to pay a commitment fee equal to 0.75% per annum of the amounts made available but unborrowed under the revolving loan. As of March 31, 2015, the Company had not borrowed any amounts pursuant the revolving loan facility.

Debt Issuance Costs

As of March 31, 2015 and December 31, 2014, the Company had \$704,000 and \$90,000, respectively, of unamortized debt issuance discount, which is offset against borrowings in long and short term debt.

For the three months ended March 31, 2015, amortization of debt issuance costs was \$49,000. Amortization of debt issuance costs was included in interest expense in our Unaudited Condensed Consolidated Statements of Comprehensive Loss for the periods presented.

Letter of Credit

In September 2012, the Company provided a \$758,000 letter of credit issued by Banc of California to the landlord of its Carlsbad, California facility. This letter of credit was secured with \$758,000 of restricted cash at March 31, 2015.

8. Leases

The Company has lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged under these arrangements were \$300,000 and \$295,000 for the three months ended March 31, 2015 and 2014, respectively. Pursuant to the Company's lease agreements, a portion of the monthly rent has been deferred. The balance of deferred rent as of March 31, 2015 and December 31, 2014 was \$1,566,000 and \$1,698,000, respectively. As of March 31, 2015, the future minimum lease payments required over the next five years under the Company's lease arrangements are as follows (in thousands):

| Fiscal Years Ending | Amount |
|------------------------------|---------|
| Remaining in 2015 | \$817 |
| 2016 | 1,116 |
| 2017 | 1,123 |
| 2018 | 1,156 |
| 2019 | 1,191 |
| Thereafter | 1,853 |
| Total minimum lease payments | \$7,256 |

9. Fair Value of Financial Instruments

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

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

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

The following table presents the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at March 31, 2015 and December 31, 2014 (in thousands):

| | March 31, 2015 | | | |
|---------------------------------------|---|---|--|----------|
| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| Money market funds (cash equivalents) | \$22,054 | \$— | \$— | \$22,054 |
| Corporate notes and bonds | — | 21,035 | — | 21,035 |
| U.S. government and agency securities | — | 10,759 | — | 10,759 |
| Commercial paper | — | 2,247 | — | 2,247 |
| | \$22,054 | \$34,041 | \$— | \$56,095 |

| | December 31, 2014 | | | |
|---------------------------------------|---|---|--|----------|
| | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| Money market funds (cash equivalents) | \$31,412 | \$— | \$— | \$31,412 |
| Corporate notes and bonds | — | 18,387 | — | 18,387 |
| U.S. government and agency securities | — | 15,264 | — | 15,264 |
| | \$31,412 | \$33,651 | \$— | \$65,063 |

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

10. Investments

The following table summarizes the Company's available-for-sale investments at March 31, 2015 and December 31, 2014 (in thousands):

| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
|---------------------------------------|-------------------|------------------------------|-------------------------------|-------------------------|
| March 31, 2015 | | | | |
| Corporate notes and bonds | \$21,044 | \$5 | \$(14) |) \$21,035 |
| U.S. government and agency securities | 10,758 | 2 | (1) |) 10,759 |
| Commercial paper | 2,247 | — | — | 2,247 |
| Total | \$34,049 | \$7 | \$(15) |) \$34,041 |
| December 31, 2014 | | | | |
| Corporate notes and bonds | \$18,408 | \$1 | \$(22) |) \$18,387 |
| U.S. government and agency securities | 15,267 | 2 | (5) |) 15,264 |
| Total | \$33,675 | \$3 | \$(27) |) \$33,651 |

The following table summarizes the maturities of the Company's available-for-sale securities at March 31, 2015 (in thousands):

| | Amortized Cost | Estimated Fair Value |
|--------------------------------------|-------------------|-------------------------|
| Due in one year or less | \$31,799 | \$31,790 |
| Due after one year through two years | 2,250 | 2,251 |
| Total | \$34,049 | \$34,041 |

11. Income Taxes

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

As of March 31, 2015, the Company recorded a full valuation allowance against all of its net deferred tax assets due to the uncertainty surrounding the Company's ability to utilize these assets in the future. Due to the Company's losses in the U.S. federal and state jurisdictions, it only records a tax provision or benefit related to minimum state tax payments or refunds in addition to foreign taxes. Provision for income taxes was \$22,000 and \$6,000 for the three months ended March 31, 2015 and 2014, respectively.

The Company is subject to taxation in the United States and in various state jurisdictions. As of March 31, 2015, the Company's tax years from 2010 to 2012 are subject to examination by the United Kingdom tax authorities related to legacy operations. Except for net operating losses generated in prior years carrying forward to the current year, as of March 31, 2015, the Company is no longer subject to U.S. federal, state, local, or foreign examinations for years before 2010.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read with our unaudited condensed consolidated financial statements for the three months ended March 31, 2015 and the notes thereto included in Part I, Item 1 of this Quarterly Report, as well as the audited financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2014, included in our Annual Report on

Form 10-K for the year ended December 31, 2014.

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management, including, without limitation, our expectations regarding our results

of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as “expect,” “anticipate,” “target,” “project,” “believe,” “goals,” “estimate,” “potential,” “predict,” “plan,” “may,” “will,” “might,” “could,” “intend,” variations of these terms and negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in or implied by any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on February 24, 2015. We assume no obligation to update these forward looking statements to reflect future events or circumstances.

Overview

Our proprietary electrochemical technology enables fast, accurate and highly sensitive detection of multiple distinct biomarkers in a single sample. Our XT-8 system received 510(k) clearance from the United States Food and Drug Administration, or FDA, and is designed to support a broad range of molecular diagnostic tests with a compact and easy-to-use workstation and disposable test cartridges. Our XT-8 system supports up to 24 independent test cartridges, each of which can be run independently, resulting in a highly convenient and flexible workflow for our target customers, which are primarily hospitals and reference laboratories. As of March 31, 2015, we had an installed base of 562 XT-8 analyzers, or placements, with our customers.

Since inception, we have incurred net losses from operations each year, and we expect to continue to incur losses for the foreseeable future. Our losses for the three months ended March 31, 2015 and 2014 were approximately \$9,869,000 and \$8,783,000, respectively. As of March 31, 2015, we had an accumulated deficit of \$272,341,000. Our operations to date have been funded principally through sales of capital stock, borrowings and cash from operations. We expect to incur increasing expenses over the next several years, principally to develop and commercialize our ePlex™ system and additional diagnostic tests, as well as to further increase our spending to manufacture, sell and market our products.

Our Products and Technology

We have a menu of eight tests for use with our XT-8 system. Four of our diagnostic tests have received FDA clearance, including our Cystic Fibrosis Genotyping Test, our Warfarin Sensitivity Test, our Thrombophilia Risk Test, and our Respiratory Viral Panel. In addition to these four FDA cleared tests, we have developed two hepatitis C virus, or HCV, genotyping tests, a 3A4/3A5 genotyping test, and a 2C19 genotyping test, versions of which are available for research use only (RUO).

In addition, we have recently completed the development stage of our ePlex system, which integrates automated nucleic acid extraction and amplification with our eSensor® detection technology to enable operators using the ePlex system to place a raw or a minimally prepared patient sample directly into our test cartridge and obtain results without any additional steps. This sample-to-answer capability is enabled by the robust nature of our eSensor® detection technology, which is not impaired by sample impurities that we believe hinder competing technologies. We have designed our ePlex system to further simplify workflow and provide powerful, cost-effective molecular diagnostics solutions to a significantly expanded group of hospitals and reference laboratories. We are currently developing seven assays for our ePlex system, which include gram-positive (GP) and gram-negative (GN) sepsis panels, a respiratory panel (RP), a gastrointestinal (GI) pathogen panel, an HCV genotyping test (HCVg), a central nervous system (CNS) panel and a fungal panel (FP). We intend to continue investing in our ePlex system and its related test menu for the foreseeable future. We are currently focusing on reliability and production scale-up to support the levels required for clinical studies and the European launch of ePlex. We expect a fourth-quarter 2015 European launch of ePlex, and we expect to submit for FDA 510(k) clearance in the first quarter of 2016.

Revenue

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

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

Cost of Revenues

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

Sales and Marketing Expenses

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

Research and Development Expenses

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

General and Administrative Expenses

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

Foreign Exchange Gains and Losses

Transactions in currencies other than our functional currency are translated at the prevailing rates on the dates of the applicable transaction. Foreign exchange gains and losses arise from differences in exchange rates during the period

between the date a transaction denominated in a foreign currency is consummated and the date on which it is settled or translated.

Interest Income and Interest Expense

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

Provision for Income Taxes

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

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

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

Results of Operations — Three months ended March 31, 2015 compared to the three months ended March 31, 2014:

| | March 31, | | | | |
|----------------|-----------|---------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Revenue | \$10,107 | \$7,913 | \$2,194 | 28 | % |

Our revenue consists primarily of revenue from the sale of test cartridges and reagents (which we refer to as consumables), with a small component from our sale of instruments and other revenue. Revenue for the quarter ended March 31, 2015 increased compared to the same quarter of 2014, due to higher consumable revenues of \$9,800,000 versus \$7,432,000 in the comparable period ended March 31, 2014. This increase in consumable revenue was primarily driven by purchases of our infectious disease assays. Pricing changes did not have a material impact on revenue during the current period.

| | March 31, | | | | |
|-----------------|-----------|---------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Cost of Revenue | \$3,991 | \$3,591 | \$400 | 11 | % |
| Gross Profit | \$6,116 | \$4,322 | \$1,794 | 42 | % |

The increase in cost of revenue for the quarter ended March 31, 2015 compared to the quarter ended March 31, 2014 was primarily related to the increase in consumables revenue in the current period. Increases in our cost of revenue were attributable to product costs of \$502,000 corresponding to volume increases and inventory reserves of \$141,000, partially offset by decreased supplies expense of \$108,000 and a \$94,000 decrease in employee-related expenses. The increase in gross profit was primarily due to higher product sales.

| | March 31, | | | | |
|---------------------|-----------|---------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Sales and Marketing | \$3,693 | \$2,979 | \$714 | 24 | % |

The increase in sales and marketing expense for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, was primarily driven by an increase in employee-related expenses of \$656,000, including increased stock-based compensation expense of \$357,000 incurred in connection with expanding our domestic and international commercial organization.

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| (in thousands) | March 31, 2015 | 2014 | \$ Change | % Change | |
|----------------------------|-------------------|---------|-----------|----------|---|
| General and Administrative | \$3,671 | \$2,933 | \$738 | 25 | % |

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The increase in general and administrative expense for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, was primarily due to an increase in employee-related expenses of \$550,000 including increased stock-based compensation expense of \$368,000, and an increase in recruitment costs of \$116,000.

| | March 31, | | | | |
|--------------------------|-----------|---------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Research and Development | \$8,779 | \$7,270 | \$1,509 | 21 | % |

The increase in research and development expense for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, was primarily due to an increase in costs associated with the development of our ePlex assays of \$1,081,000, and a \$229,000 increase in patent prosecution and other related legal fees.

| | March 31, | | | | |
|------------------------|-----------|------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Other Income (Expense) | \$180 | \$83 | \$97 | 117 | % |

Other income (expense) represents non-operating income and expense, including, but not limited to, earnings on cash and cash equivalents, restricted cash, marketable securities, and interest expense related to debt. The increase in other income (expense) for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, was due primarily to one-time income of \$223,000 received from the release of escrowed proceeds related to our sale of preferred stock of Advanced Liquid Logic, Inc. shares in fourth quarter of 2014, which was partially offset by an increase in interest expense related to the amortization of debt issuance costs of \$71,000 and a \$51,000 decrease in interest earned on marketable securities.

| | March 31, | | | | |
|----------------------------|-----------|------|-----------|----------|---|
| (in thousands) | 2015 | 2014 | \$ Change | % Change | |
| Provision for Income Taxes | \$22 | \$6 | \$16 | 267 | % |

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

Liquidity and Capital Resources

To date, we have funded our operations primarily from the sale of our common stock, borrowings and cash from operations. We have incurred net losses from continuing operations each year and have not yet achieved profitability. At March 31, 2015, we had \$68,706,000 of working capital, including \$70,954,000 in cash, cash equivalents, and short-term investments.

Cash Flows

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

| | March 31, | | |
|--|-----------|-----------|---|
| Three months ended (in thousands): | 2015 | 2014 | |
| Net cash used in operating activities | \$(8,265) | \$(6,384) |) |
| Net cash used in investing activities | (1,185) | (1,439) |) |
| Net cash provided by (used in) financing activities | 9,517 | (17) |) |
| Effect of exchange rate on cash | (9) | 0 |) |
| Net increase (decrease) in cash and cash equivalents | \$58 | \$(7,840) |) |

Cash flows used in operating activities

Net cash used in operating activities increased \$1,881,000 for the three months ended March 31, 2015 compared to the three months ended March 31, 2014. The increased use of cash during the first three months of 2014 was primarily due to an increase in our net loss of \$1,086,000, which was partially offset by increases in stock-based compensation of \$950,000 related to the increase in employees to support our domestic and international expansion.

Cash flows used in investing activities

Net cash used in investing activities decreased by \$254,000 for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, primarily due to increases in maturities of short-term investments of \$7,100,000 which was partially offset by a \$5,276,000 decrease in proceeds from sales of marketable securities and an increase in purchases of marketable securities of \$1,758,000.

Cash flows provided by (used in) financing activities

Net cash provided by (used in) financing activities increased by \$9,534,000 for the three months ended March 31, 2015, compared to the three months ended March 31, 2014, primarily due to the \$10,000,000 we borrowed in March 2015 under our Loan and Security Agreement with General Electric Capital Corporation and certain other lenders.

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

- the level of revenues and the rate of our revenue growth;
- change in demand from our customers;
- the level of expenses required to expand our U.S. and international commercial (sales and marketing) activities;
- the level of research and development investment required to develop and commercialize our ePlex™ system and related test menu and maintain our XT-8 system;
- our need to acquire or license complementary technologies;
- the costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- competing technological and market developments; and
- changes in regulatory policies or laws that affect our operations.

Loan and Security Agreement

In January 2015, we entered into a Loan and Security Agreement, or the Agreement, with General Electric Capital Corporation, or GECC, and certain other financial institutions, as lenders, pursuant to which we obtained (a) up to \$35,000,000 in a series of term loans and (b) a revolving loan in the maximum amount of \$5,000,000. Under the terms of the Agreement, we may, subject to certain conditions, borrow:

- \$10,000,000 on or before March 31, 2015, which we borrowed in March 2015;
- an additional \$10,000,000, subject to our satisfaction of regulatory requirements necessary to CE Mark its ePlex™ system in Europe by a specified date;
- an additional \$15,000,000, subject to our satisfaction of FDA 510(k) market clearance for the sale of our ePlex™ system in the United States by a specified date; and
- up to \$5,000,000 in the form of a revolving loan, which is subject to a defined borrowing base as set forth in the Agreement.

Pursuant to the terms of the Agreement, the lenders are granted a security interest in (a) all of our personal property, other than intellectual property (which is subject to a negative pledge), but including our rights to payment in respect of intellectual property, (b) the stock of all of our domestic subsidiaries, and (c) 65% of the voting stock and 100% of the non-voting stock of each of our non-U.S. subsidiaries.

The Agreement contains customary affirmative and negative covenants, including, without limitation, delivering reports and notices relating to our financial condition and certain regulatory events and intellectual property matters, as well as limiting the creation of liens, the incurrence of indebtedness, and the making of certain investments, payments and acquisitions, other than as specifically permitted by the Agreement.

Letter of Credit

In September 2012, we provided a \$758,000 letter of credit issued by Banc of California to the landlord of our Carlsbad, California facility. This letter of credit was secured with \$758,000 of restricted cash at March 31, 2015. Although we do not currently anticipate requiring additional capital, if additional capital is required, we cannot be certain that it will be available when needed or that our actual cash requirements will not be greater than anticipated. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us.

Contractual Obligations

Our contractual obligations as of December 31, 2014 are summarized in our Annual Report on Form 10-K for the year ended December 31, 2014. In connection with the Loan and Security Agreement, we borrowed \$10,000,000 during the three months ended March 31, 2015. The principal and applicable interest is due in full on or before January 12, 2019.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our estimates on an ongoing basis, including those related to doubtful accounts, inventories, valuation of intangibles and other long-term assets, income taxes, and stock-based compensation. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ from these estimates. Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and there have been no material changes to such policies or estimates during the three months ended March 31, 2015.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risks during the quarter ended March 31, 2015.

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

Interest Rate Risk

As of March 31, 2015, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an insignificant pre-tax impact on our results of operations.

Foreign Currency Exchange Risks

All of our operating facilities are located within the United States. We are a U.S. entity and our functional currency is the U.S. dollar. Virtually all of our revenues are based in the United States. We currently have no material operations outside of the United States, which significantly diminishes the extent of any foreign currency exchange risk we currently face.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports we file under the Exchange Act is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer, with the participation of management, concluded that, as of March 31, 2015, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

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

PART II-OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

There have been no material changes to our risk factors during the three months ended March 31, 2015. For additional information regarding risk factors, refer to Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

GENMARK DIAGNOSTICS, INC.

Date: May 5, 2015

By: /s/ HANY MASSARANY
Hany Massarany
Chief Executive Officer, President and Director
(principal executive officer)

Date: May 5, 2015

By: /s/ SCOTT MENDEL
Scott Mendel
Chief Financial Officer
(principal financial and accounting officer)

EXHIBIT INDEX

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

| Exhibit | Description |
|---------|--|
| 3.1 | Certificate of Incorporation (Incorporated by reference to our Registration Statement on Form S-1 (File No. 333-165562) filed with the SEC on March 19, 2010). |
| 3.2 | Amended and Restated Bylaws (Incorporated by reference to our Current Report on Form 8-K filed with the SEC on October 31, 2014). |
| 10.1 | Loan and Security Agreement dated as of January 12, 2015 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, General Electric Capital Corporation, and certain other financial institutions as lenders. * |
| 10.2 | Form of Market Stock Units Grant Notice and Award Agreement. † |
| 10.3 | The GenMark Diagnostics Inc. 2015 Bonus Plan (incorporated by reference to our Current Report on Form 8-K filed with the SEC on February 25, 2015). † |
| 31.1 | Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 31.2 | Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 32.1 | Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350. |
| 101.INS | XBRL Instance Document. |
| 101.SCH | XBRL Taxonomy Extension Schema Document. |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. |
| † | Management compensation plan. |
| * | GenMark has requested confidential treatment with respect to certain portions of this exhibit. |