GenMark Diagnostics, Inc.
Form 10-Q
April 30, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2019
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 (State or other jurisdiction of incorporation or organization)	27-2053069 (I.R.S. Employer Identification No.)
5964 La Place Court Carlsbad, California (Address of principal executive offices)	92008-8829 (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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨
Emerging growth 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

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

The number of outstanding shares of the registrant’s common stock on April 25, 2019 was 57,028,553.

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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, 2019	December 31, 2018
ASSETS:		
Current Assets:		
Cash and cash equivalents	$35,304	$ 36,286
Short-term marketable securities	13,118	8,882
Accounts receivable, net of allowances of $75 and $75, respectively	9,168	11,534
Inventories, net	9,391	10,244
Current operating lease right-of-use assets	1,260	—
Prepaid expenses and other current assets	1,396	1,483
Total current assets	69,637	68,429
Property and equipment, net	19,927	21,070
Intangible assets, net	1,875	2,023
Restricted cash	758	758
Noncurrent operating lease right-of-use assets	3,734	—
Other long-term assets	729	701
Total assets	$96,660	$ 92,981
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$8,508	$ 9,886
Accrued compensation	5,111	7,358
Current operating lease liability	1,801	—
Other current liabilities	2,321	3,043
Total current liabilities	17,741	20,287
Deferred rent	—	2,996
Long-term debt	47,821	36,042
Noncurrent operating lease liability	6,591	—
Other noncurrent liabilities	70	109
Total liabilities	72,223	59,434
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 57,026 and 56,240 shares issued and outstanding, respectively	6	6
Additional paid-in capital	503,318	500,344
Accumulated deficit	(478,963)	(466,883)
Accumulated other comprehensive income	76	80
Total stockholders’ equity	24,437	33,547
Total liabilities and stockholders’ equity	$96,660	$ 92,981

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,	
	2019	2018
Revenue:		
Product revenue	$21,371	$20,576
License and other revenue	162	69
Total revenue	21,533	20,645
Cost of revenue	15,670	16,480
Gross profit	5,863	4,165
Operating expenses:		
Sales and marketing	5,909	5,402
General and administrative	4,521	4,133
Research and development	6,343	5,420
Total operating expenses	16,773	14,955
Loss from operations	(10,910)	(10,790)
Other income (expense):		
Interest income	133	187
Interest expense	(1,276)	(788)
Other income (expense)	(11)	(12)
Total other income (expense)	(1,154)	(613)
Loss before provision for income taxes	(12,064)	(11,403)
Income tax expense	16	20
Net loss	$(12,080)	$(11,423)
Net loss per share, basic and diluted	$(0.21)	$(0.21)
Weighted average number of shares outstanding, basic and diluted	56,581	55,205
Other comprehensive loss:		
Net loss	$(12,080)	$(11,423)
Other comprehensive income/(loss):		
Foreign currency translation adjustments, net of tax	(6)	34
Net unrealized gains (losses) on marketable securities, net of tax	2	8
Total other comprehensive income/(loss)	(4)	42
Total comprehensive loss	$(12,084)	$(11,381)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Operating activities:		
Net loss	$(12,080)	$(11,423)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,812	1,740
Net amortization/(accretion) of premiums/discounts on investments	(21)	(42)
Amortization of deferred debt issuance costs	366	290
Stock-based compensation	2,544	2,724
Non-cash inventory adjustments	634	449
Other non-cash adjustments	(16)	84
Changes in operating assets and liabilities:		
Accounts receivable	2,355	2,566
Inventories	(131)	(526)
Prepaid expenses and other assets	—	760
Accounts payable	(1,043)	(1,361)
Accrued compensation	(2,475)	(992)
Other current and non-current liabilities	(126)	(321)
Net cash used in operating activities	(8,181)	(6,052)
Investing activities:		
Purchases of property and equipment	(333)	(465)
Purchases of marketable securities	(12,014)	(7,900)
Maturities of marketable securities	7,800	18,000
Net cash provided by (used in) investing activities	(4,547)	9,635
Financing activities:		
Principal repayment of borrowings	(35,116)	(22)
Proceeds from borrowings	50,000	—
Payments associated with debt issuance	(3,588)	(20)
Proceeds from stock option exercises	430	17
Net cash provided by (used in) financing activities	11,726	(25)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	20	(34)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(982)	3,524
Cash, cash equivalents, and restricted cash at beginning of year	37,044	27,512
Cash, cash equivalents, and restricted cash at end of period	$36,062	$31,036
Non-cash investing and financing activities:		
Transfer of systems (from) to property and equipment into (from) inventory	$351	$569
Property and equipment included in accounts payable	$36	$147
Supplemental cash flow information:		
Cash paid for income taxes, net	$44	$33
Cash paid for interest	$761	$508

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock Shares	Par Value	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balance—December 31, 2018	56,240	6	500,344	80	(466,883)	33,547
Stock-based compensation expense	—	—	2,544	—	—	2,544
Restricted stock awards issued, net of cancellations	715	—	—	—	—	—
Shares issued under stock-based compensation plans	71	—	430	—	—	430
Net loss	—	—	—	—	(12,080)	(12,080)
Foreign currency translation adjustments	—	—	—	(6)	—	(6)
Unrealized gain on marketable securities	—	—	—	2	—	2
Balance—March 31, 2019	57,026	$ 6	$ 503,318	$ 76	$ (478,963)	$ 24,437

See accompanying notes to unaudited condensed consolidated financial statements.

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GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock Shares	Par Value	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
Balance—December 31, 2017	55,066	6	487,525	8	(416,385)	71,154
Stock-based compensation expense	—	—	2,724	—	—	2,724
Restricted stock awards issued, net of cancellations	342	—	—	—	—	—
Shares issued under stock-based compensation plans	4	—	17	—	—	17
Net loss	—	—	—	—	(11,423)	(11,423)
Reimbursement of offering costs	—	—	40	—	—	40
Foreign currency translation adjustments	—	—	—	34	—	34
Unrealized gain on marketable securities	—	—	—	8	—	8
Balance—March 31, 2018	55,412	$ 6	$ 490,306	$ 50	$ (427,808)	$ 62,554

See accompanying notes to unaudited condensed consolidated financial statements.

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

1. Organization and Basis of Presentation

GenMark Diagnostics, Inc., the Company or GenMark, was formed by Osmetech plc as a Delaware corporation in February 2010, and had no operations prior to its initial public offering, which was completed in June 2010. The Company is a provider of multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care.

Basis of Presentation and Principles of Consolidation
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 the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the SEC on February 25, 2019. 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.

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

The Company has experienced net losses and negative cash flows from operating activities since its inception and had an accumulated deficit of $478,963,000 as of March 31, 2019. 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. As of March 31, 2019, the Company had available cash, cash equivalents, and marketable securities of $48,422,000 and working capital of $51,896,000 available to fund future operations. The Company has prepared cash flow forecasts which indicate, based on the Company's current cash resources available and working capital, that the Company will have sufficient resources to fund its operations for at least one year after the date the financial statements are issued.

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

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.

In June 2018, the FASB issued Accounting Standards Update, or ASU 2018-07, Compensation - Stock Compensation (Topic 718), which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year), with early adoption permitted. The Company adopted this new standard in the second quarter of 2018 and determined its application did not have a material impact on the Company's unaudited condensed consolidated financial statements.

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In February 2016, the FASB issued ASU 2016-02, Leases, which outlines a comprehensive lease accounting model and supersedes the current lease guidance. The new guidance requires lessees to recognize lease liabilities and corresponding right-of-use, or ROU, assets for all leases with lease terms of greater than 12 months. The guidance also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new guidance must be adopted using the modified retrospective approach and is effective for annual periods beginning after December 15, 2018. The Company adopted the new standard in the first quarter of 2019 using the package of transition practical expedients. The Company recognized current and non-current ROU assets of $1,261,000 and $3,836,000, respectively, and current and non-current lease liabilities of $1,780,000 and $6,832,000 upon adoption. Deferred rent is now presented as an offset to the Company's current and non-current operating lease ROU assets. The new lease standard did not have a material impact on the Company's unaudited condensed consolidated statements of operations, cash flows, or stockholders' equity.

Revenue

The Company recognizes revenue from operations through the sale of products and other services. Product revenue comprises the sale of diagnostic tests and instruments.

Revenue is recognized when control of products and services is transferred to the customer in an amount that reflects the consideration that the Company expects to receive from the customer in exchange for those products and services. This process involves identifying the contract with the customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Revenue from product sales is recognized generally upon shipment to the end customer, which is when control of the product is deemed to be transferred. Invoicing typically occurs upon shipment and the term between invoicing and when payment is due is not significant. Revenue from instrument services is recognized as the services are rendered, typically evenly over the contract term.

Revenue is recorded net of discounts and sales taxes collected on behalf of governmental authorities. Employee sales commissions are recorded as selling, general and administrative expenses when incurred or amortized over the estimated contract term when resulting from new contract acquisition efforts.

The Company allocates contract price to each performance obligation in proportion to its stand-alone selling price. The stand-alone selling price is determined by the Company's best estimate of stand-alone selling price using average selling prices over a rolling 12-month period along with a specific assessment of any unique circumstances of the contract. For those products for which there is limited sales history, the Company makes price determination based on similar product sales data.

The following table represents disaggregated revenue by source (in thousands):

	Three Months Ended March 31,	
	2019	2018
Revenue Source:		
ePlex product revenue	$15,651	$11,922

XT-8 product revenue	5,720	8,654
Total product revenue	21,371	20,576
License and other revenue	162	69
Total revenue	$21,533	$20,645

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash on deposit with banks, money market instruments and certificates of deposit with original maturities of three months or less at the date of purchase. Marketable securities consist of certificates of deposits that mature in greater than three months. Marketable securities are accounted for as "available-for-sale" with the carrying amounts

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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 comprised $758,000 as of both March 31, 2019 and December 31, 2018, 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 instruments 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 its warranty reserve and adjusts the amount as appropriate.

Intangible Assets
Intangible assets comprise 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 ten 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 net realizable value 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 net realizable 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 - 5 years
Office equipment	3 - 7 years
Leasehold improvements	over the shorter of the remaining life of the lease or the useful economic life of the asset

Leases

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The Company determines if an arrangement is a lease at inception. Operating leases are included in current and noncurrent operating lease ROU assets and current and noncurrent operating lease liabilities in the consolidated balance sheets. Finance leases are included in other current assets and liabilities and other non-current assets and liabilities in the consolidated balance sheets.

ROU assets represent the Company’s right to use an underlying asset over the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at commencement date based on the present value of the Company’s lease payments over the lease term. As most of the Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date to determine the present value of its lease payments. ROU assets are recognized at the commencement date based upon the initial measurement of the operating lease liability less any lease incentives received.

The Company’s lease agreements can include both lease and non-lease components. The Company accounts for each lease component separately from the non-lease components within its lease agreements.

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. 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 calculations of diluted net loss per share for each of the three months ended March 31, 2019 and 2018 did not include the effects of the following stock options and other equity 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,	
	2019	2018
Options outstanding to purchase common stock	2,215	2,454
Other unvested equity awards	4,007	3,759
Total	6,222	6,213

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3. Stock-Based Compensation

Equity awards 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. 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, directors and non-employee advisors in exchange for services under the Company's 2010 Equity Incentive Plan, or the 2010 Plan, and employee stock purchases under the Company's Amended and Restated 2013 Employee Stock Purchase Plan, or the ESPP. Employee participation in the 2010 Plan is at the discretion of the Compensation Committee of the Board of Directors of the Company. Each equity award grant reduces the number of shares available for grant under the 2010 Plan. Stock-based compensation expense is recorded in cost of sales, sales and marketing, research and development, and/or general and administrative expenses based on the employee's respective function. During the three months ended March 31, 2019 and 2018, aggregate stock-based compensation expense was $2,544,000 and $2,724,000, respectively.

Stock Options
The fair value of stock options granted is derived from the Black-Scholes Option Pricing Model, which uses several judgment-based variables to calculate the expense. The inputs include the expected term of the stock option, the expected volatility and other factors.

• Expected Term. Expected term represents the period that the stock-based awards are expected to be outstanding and is determined by using the simplified method.
• Expected Volatility. Expected volatility represents the estimated volatility in the Company’s 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 has 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.

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 common stock on the NASDAQ Global Market on the grant date and generally vest over a period of four years. Stock options are generally exercisable for a period of up to ten years after grant and are typically forfeited if employment is terminated before the options vest.

The following table summarizes stock option activity during the three months ended March 31, 2019:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2018	2,439,914	$ 9.57
Granted	—	$ —
Exercised	(71,833)	$ 5.98
Cancelled	(153,493)	$ 12.15
Outstanding at March 31, 2019	2,214,588	$ 9.51
Vested and expected to vest at March 31, 2019	2,214,581	$ 9.51
Exercisable at March 31, 2019	2,214,327	$ 9.51

Options that were exercisable as of March 31, 2019 had a remaining weighted average contractual term of 3.77 years, and an aggregate intrinsic value of $1,429,000. As of March 31, 2019, there were 2,214,588 stock options outstanding, which had a remaining weighted average contractual term of 3.77 years and an aggregate intrinsic value of $1,429,000. No stock options were granted during the three months ended March 31, 2019.

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Restricted Stock Units

Restricted stock units granted under the 2010 Plan generally vest over a period of between one and four years and are typically forfeited if service to the Company ceases before the restricted stock units vest. The compensation expense related to the restricted stock units is calculated as the fair market value of the Company's stock on the grant date and is adjusted for estimated forfeitures. Restrictions expire after the grant date in accordance with specific provisions in the applicable award agreement.

The Company’s restricted stock unit activity for the three months ended March 31, 2019 was as follows:

	Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	2,665,708	$ 6.12
Granted	1,352,750	$ 6.70
Vested	(569,050)	$ 5.37
Cancelled	(182,539)	$ 6.55
Unvested at March 31, 2019	3,266,869	$ 6.47

As of March 31, 2019, there was $15,034,000 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.91 years. The total fair value of restricted stock units that vested during the three months ended March 31, 2019 and 2018 was $4,058,000 and $1,523,000, respectively.

Market-Based Stock Units

The Company issued market-based stock units in each of February 2019, 2018, and 2017, which may result in the recipient receiving shares of stock equal to 200% of the target number of units granted. The vesting and issuance of Company stock depends on the Company's stock performance as compared to the NASDAQ Composite Index over the three-year period following the grant, subject to the recipient's continued service with the Company. As of March 31, 2019, there was $3,847,000 of unrecognized stock-based compensation expense related to market-based stock unit awards, which is expected to be recognized over a weighted average period of 2.15 years.

The Company’s market-based stock unit activity for the three months ended March 31, 2019 was as follows:

	Market-Based Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	328,739	$ 10.03
Units Granted	440,000	$ 10.21
Cancelled	(28,334)	$ 9.39
Unvested at March 31, 2019	740,405	$ 10.16

The fair value of these market-based stock units was estimated on the grant date using the Monte Carlo Simulation Valuation Model, which estimates the potential outcome of achieving the market condition based on simulated future stock prices, with the following assumptions for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,			
	2019		2018	
Expected volatility	64	%	65	%
Risk-free interest rate	2.50	%	2.40	%
Expected dividend	—	%	—	%
Weighted average fair value	$10.11 - $10.31		$ 7.19	

Employee Stock Purchase Plan

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The Company's stockholders approved the ESPP in May 2013. In May 2018, the Company's stockholders approved the amendment and restatement of the ESPP, which increased the shares authorized for issuance under the ESPP from 650,000 shares to 1,750,000 shares.

The price at which stock is purchased under the ESPP is equal to 85% of the fair market value of the Company's common stock on the first or the last day of the offering period, whichever is lower. Generally, each offering under the ESPP will be for a period of six months as determined by the Company's Board of Directors; provided that no offering period may exceed 27 months. Employees may invest up to 10% of their qualifying gross compensation through payroll deductions. In no event may an employee purchase more than 1,500 shares of common stock during any six-month offering period. As of March 31, 2019, there were 940,493 shares of common stock available for issuance under the ESPP. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation; therefore, stock-based compensation expense related to the ESPP has been recorded during each of the three months ended March 31, 2019 and 2018.

Stock-Based Compensation Expense Recognition

Stock-based compensation was recognized in the unaudited condensed consolidated statements of comprehensive loss as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of revenue	$204	$187
Sales and marketing	619	645
Research and development	423	627
General and administrative	1,298	1,265
Total stock-based compensation expense	$2,544	$2,724

Stock-based compensation capitalized during the periods presented was not material and there was no unrecognized tax benefit related to stock-based compensation for either of the three months ended March 31, 2019 and 2018.

4. Condensed Consolidated Financial Statement Details

The following tables show the Company's unaudited condensed consolidated financial statement details as of March 31, 2019 and December 31, 2018 (in thousands):

Inventory

	March 31, 2019	December 31, 2018
Raw materials	$ 2,344	$ 2,449
Work-in-process	3,131	3,349
Finished goods	3,916	4,446
Total inventories	$ 9,391	$ 10,244

Property and Equipment, Net

	March 31, 2019	December 31, 2018
Property and equipment — at cost:		
Machinery and laboratory equipment	$ 15,013	$ 15,206
Instruments	15,406	15,089
Office equipment	2,135	2,114
Leasehold improvements	10,759	10,648
Total property and equipment — at cost	43,313	43,057
Less: accumulated depreciation	(23,386)	(21,987)
Property and equipment, net	$ 19,927	$ 21,070

Accrued Warranty

The following table shows changes in the Company's accrued warranties for each of the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
Beginning accrued warranty balance	$ 330	$ 470
Warranty expenses incurred	(444)	(516)
Provisions	487	464
Ending accrued warranty balance	$ 373	$ 418

5. Intangible Assets, net

Intangible assets as of each of March 31, 2019 and December 31, 2018 comprised the following (in thousands):

	March 31, 2019			December 31, 2018		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Licensed intellectual property	$4,750	$ (2,875)	$ 1,875	$4,750	$ (2,727)	$ 2,023

In July 2012, the Company entered into a development collaboration and license agreement with Advanced Liquid Logic, Inc., or ALL, which was acquired by Illumina, Inc. in July 2013. Under the terms of the agreement, the Company established a collaborative program to develop in-vitro diagnostic products incorporating ALL’s proprietary electro-wetting technology in conjunction with the Company’s electrochemical detection technology.

Intellectual property licenses have a weighted average remaining amortization period of 3.18 years as of March 31, 2019. Amortization expense for these licenses was $148,000 and $149,000 for the three months ended March 31, 2019 and 2018, respectively.

Estimated future amortization expense for these licenses is as follows (in thousands):

Fiscal Years Ending	Future Amortization Expense
Remaining in 2019	$ 445
2020	593
2021	593
2022	244
Total	$ 1,875

6. Marketable Securities

The following table summarizes the Company’s marketable securities as of each of March 31, 2019 and December 31, 2018 (in thousands):

March 31, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 4,992	$ —	$ (1)	$ 4,991
U.S. government and agency securities	6,149	—	—	6,149
Commercial paper	1,979	—	(1)	1,978
Total	$ 13,120	$ —	$ (2)	$ 13,118

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 6,393	$ —	$ (4)	$ 6,389
Commercial paper	2,493	—	—	2,493
Total	$ 8,886	$ —	$ (4)	$ 8,882

All of the Company's marketable securities have a maturity of one year or less.

7. 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 and the valuation approach applied to each class of financial instruments as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents				
Money market funds	$6,004	$ —	$ —	$6,004
Corporate notes and bonds	—	1,549	—	1,549
U.S. government and agency securities	—	1,999	—	1,999
Commercial paper	—	5,285	—	5,285
Marketable securities				
Corporate notes and bonds	—	4,991	—	4,991
U.S. government and agency securities	—	6,149	—	6,149
Commercial paper	—	1,978	—	1,978
Total	$6,004	$ 21,951	$ —	$27,955

	December 31, 2018			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents				
Money market funds	$8,953	$ —	$ —	$8,953
Marketable securities				
Corporate notes and bonds	—	6,389	—	6,389
U.S. government and agency securities	—	2,493	—	2,493
Total	$8,953	$ 8,882	$ —	$17,835

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

8. Long-term debt

As of March 31, 2019 and December 31, 2018, long-term debt consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Term Loans		
Term Loan A - 6.9% interest	$—	$ 7,619
Term Loan B - 6.9% interest	—	7,619
Term Loan C - 7.4% interest	—	12,000
Term Loan D - 8.8% interest	—	663
Term Loan E - 8.8% interest	—	7,098
Term Loan - 8.4% interest	50,000	—
Final fee obligation	2,975	3,288
Unamortized issuance costs	(5,154)	(2,245)
Total debt, net	47,821	36,042
Current portion of long-term debt	—	—
Long-term debt	$47,821	$ 36,042

Term Loans
In January 2015, the Company entered into a Loan and Security Agreement, or the LSA, with Solar Capital Partners (as successor-in-interest to General Electric Capital Corporation), and certain other financial institutions party thereto, as lenders. and certain other financial institutions party thereto, as lenders. Pursuant to the LSA and its subsequent amendments, the Company borrowed $42,762,000 in a series of term loans and had the ability to borrow against a revolving loan in the maximum amount of $5,000,000. During the term of the LSA, the term loans thereunder accrued interest at a rate equal to (a) the greater of 1.00% or the three 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 borrowed all $42,762,000 under the term loans as provided in the LSA, and the Company did not borrow any of the $5,000,000 available under the revolving loan.

On February 1, 2019, or the Effective Date, the Company entered into a new Loan and Security Agreement, or the New LSA, with Solar Capital Ltd. and certain other financial institutions, or, collectively, the Lenders. Pursuant to the New LSA, the Lenders are providing the Company with up to $65,000,000 in a series of term loans, or, collectively, the Term Loans, of which $50,000,000, or the Tranche 1 Loan, was funded on the Effective Date. An additional $15,000,000, or the Tranche 2 Loan, is available to be funded at the Company's option, but no later than December 31, 2019, provided that the Company achieves a designated amount of product revenues on a trailing six-month basis.

On the Effective Date, approximately $38,800,000 of the proceeds from the Tranche 1 Loan were used by the Company to repay all outstanding principal, interest, related fees, and other obligations under the LSA, with the remaining borrowings to be used to satisfy the Company's working capital needs and for other general business purposes. The Company accounted for the repayment of its obligations under the LSA as a debt modification. The Company has capitalized the issuance costs it incurred when entering into the New LSA, which are being amortized over the remaining term of the New LSA.

The Term Loans will accrue interest at a floating per annum rate in effect from time-to-time equal to (a) the greater of 2.51% or the one-month LIBOR rate then in effect as of the applicable payment date, plus (b) 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 February 28, 2021, or the Interest Only Period. If the Company exercises its option to borrow the Tranche 2 Loan and the Company achieves an additional designated amount of product revenues on a trailing six-month basis on or before December 31, 2020, then the Interest Only Period may, at the Company's election, be extended for both Term Loans through February 28, 2022. Following the Interest Only Period (as the same may be extended pursuant to the terms of the New LSA), 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 February 1, 2023, or the Final Maturity Date.

Under the New LSA, 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, dividends, payments and acquisitions, other than as specifically permitted by the New LSA. As of March 31, 2019, the Company was in compliance with all covenants under the LSA.

The New LSA also contains customary events of default (subject, in certain instances, to specified cure periods), including, but not limited to, the failure to make payments of interest or premium when due, the failure to comply with certain covenants and agreements specified in the New LSA, and the occurrence of a material adverse change, certain regulatory events, or certain insolvency events. Upon the occurrence of an event of default, the Lenders may declare all outstanding principal and accrued but unpaid interest under the New LSA immediately due and payable and may exercise the other rights and remedies as set forth in the New LSA.

Debt Issuance Costs

As of March 31, 2019 and December 31, 2018, the Company had $5,154,000 and $2,245,000, respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt.

Amortization of debt issuance costs was $366,000 and $290,000 for the three months ended March 31, 2019 and 2018, respectively. Amortization of debt issuance costs is included in interest expense in the Company's 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 executive office facility in Carlsbad, California. This letter of credit was secured with $758,000 of restricted cash as of March 31, 2019.

9. Leases

The Company has operating and finance lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged under these arrangements was $526,000 and $427,000 for the three months ended March 31, 2019 and 2018, respectively.

Pursuant to the adoption of the new lease standard, the Company reported current and noncurrent operating lease ROU assets of $1.3 million and $3.7 million, respectively, and current and noncurrent operating lease liabilities of $1.8 million and $6.6 million, respectively, as of March 31, 2019. The Company reported current and noncurrent deferred rent under the existing lease standard of $520,000 and $2,996,000, respectively, at December 31, 2018. The Company's operating lease liabilities were measured at a weighted average discount rate of 11.2% and have a weighted average remaining term of 6.55 years.

As of March 31, 2019, the future minimum lease payments required over the next five years under the Company's lease arrangements are as follows (in thousands):

Fiscal Years Ending	Future Minimum Lease Payments
Remaining in 2019	$ 1,504
2020	1,997
2021	2,015
2022	2,077
2023	1,939
Thereafter	2,084

Total	$ 11,616

10. 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, 2019, the Company recorded a full valuation allowance against all of its net deferred tax assets due to the uncertainty surrounding the Company’s ability to utilize these assets in the future. Due to the Company's losses, it only records a tax provision or benefit related to uncertain tax positions and related interest and minimum tax payments or refunds. The Company recorded income tax expense of $16,000 and $20,000 for the three months ended March 31, 2019 and 2018, respectively.

The Company is subject to taxation in the United States and in various state and foreign jurisdictions. The Company's federal and state tax returns since inception are subject to examination due to the carryover of net operating losses. As of March 31, 2019, the Company’s tax years from 2011 through 2012 are subject to examination by the United Kingdom tax authorities related to legacy operations. The statute of limitations for the assessment and collection of income taxes related to other foreign tax returns varies by country. In the foreign countries where we have operations, these time periods generally range from three to five years after the year for which the tax return is due or the tax is assessed.

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

Forward Looking Statements

The following discussion of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements for the three months ended March 31, 2019 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 included in our Annual Report on Form 10-K for the year ended December 31, 2018.

This Management’s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management, including, without limitation, our expectations regarding our results of operations, sales and marketing expenses, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as “expect,” “anticipate,” “target,” “project,” “believe,” “goals,” “estimate,” “potential,” “pre “may,” “will,” “might,” “could,” “intend,” variations of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in or implied by any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed under the heading “Risk Factors” in Part II, Item 1A of this Quarterly Report. We assume no obligation to update these forward looking statements to reflect future events or circumstances.

Trademarks and Trade Names

GenMark®, eSensor®, XT-8® and ePlex® and our other logos and trademarks are the property of GenMark Diagnostics, Inc. or its subsidiaries. All other brand names or trademarks appearing in this Quarterly Report are the property of their respective holders. Our use or display of other parties’ trademarks, trade dress or products in this Quarterly Report does not imply that we have a relationship with, or the endorsement or sponsorship of, the trademark or trade dress owners.

Overview

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, 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. Following the reorganization, Osmetech became a wholly-owned subsidiary controlled by GenMark, and the former shareholders of Osmetech received shares of GenMark. Any historical discussion of GenMark relates to Osmetech and its consolidated subsidiaries prior to the reorganization. In September 2012, GenMark placed Osmetech into liquidation to simplify its corporate structure. The liquidation of Osmetech was competed in the fourth quarter of 2013.

We are a molecular diagnostics company focused on developing and commercializing multiplex solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. We currently develop and commercialize high-value, simple to perform, clinically relevant multiplex molecular tests based on our proprietary eSensor electrochemical detection technology.

Since inception, we have incurred net losses from operations each year, and we expect to continue to incur losses for the foreseeable future. Our net losses for the three months ended March 31, 2019 and 2018 were approximately $12,080,000 and $11,423,000, respectively. As of March 31, 2019, we had an accumulated deficit of $478,963,000. 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 expand our diagnostic test menu for our ePlex system, as well as to increase our manufacturing capabilities and domestic and international commercial organization.

Our Products and Technology

We offer our ePlex sample-to-answer instrument and Respiratory Pathogen (RP) Panel, Blood Culture Identification Gram-Positive (BCID-GP) Panel, BCID-GN Panel, and BCID-FP Panel for sale in the United States and internationally. We are also developing our ePlex Gastrointestinal Pathogen Panel for the detection of pathogens associated with gastrointestinal infections. We continue to actively evaluate the development of additional assay panels that we believe will meet important, unmet clinical needs, which our ePlex system is uniquely positioned to address.

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We offer four FDA-cleared diagnostic tests which run on our XT-8 instrument: our Respiratory Viral Panel; our Cystic Fibrosis Genotyping Test; our Warfarin Sensitivity Test; and our Thrombophilia Risk Test. We also offer a Hepatitis C (HCV) Genotyping Test and associated custom manufactured reagents, as well as a 2C19 Genotyping Test, each of which is available for use with our XT-8 instrument for research use only (RUO).

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

Cost of Revenues
Cost of revenues includes the cost of materials, direct labor, and manufacturing overhead costs used in the manufacture of our consumable tests, including royalties on product sales. Cost of revenues also includes depreciation on revenue generating instruments that have been placed with our customers under a reagent rental agreement, cost of instruments sold to customers, amortization of licenses related to our products, and other costs such as warranty, royalty, and customer and product technical support. Any 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 instruments are procured from contract manufacturers. We expect our cost of revenues to increase as we place additional instruments and manufacture and sell additional diagnostic panels; however, over time, we expect our cost per unit to decrease as production volume increases, manufacturing efficiencies are realized, improvements to procurement practices are made, product reliability increases, and other improvements decrease costs.

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, product samples, and trade show expenses. We expect sales and marketing expenses to continue to increase as we scale-up our domestic and international commercial efforts and expand our customer base.

Research and Development Expenses
Research and development expenses primarily include costs associated with the development and expansion of our ePlex instrument's diagnostic 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 consist of salaries, benefits, stock-based compensation, outside design and consulting services, laboratory supplies, costs of consumables and materials used in product development, contract research organization costs, and clinical studies and facility costs. We expense all research and development expenses in the periods in which they are incurred.

General and Administrative Expenses
Our general and administrative expenses include costs associated with 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, 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.

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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, 2019 compared to the three months ended March 31, 2018:

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Revenue	$21,533	$20,645	$ 888	4 %

Our revenue consists primarily of revenue from the sale of test cartridges (which we refer to as consumables), instruments, and other revenues.

Revenue increased by $888 thousand or 4%, during the three months ended March 31, 2019 when compared to the same period of the prior year, primarily driven by growth in ePlex product revenue which features a higher selling price due to the the additional technology and features of its sample-to-answer capabilities. For the three months ended March 31, 2019, ePlex product revenue increased by $3.7 million to $15.7 million due to both new customers adopting ePlex and the conversion of existing XT-8 customers to our ePlex system for respiratory testing. ePlex consumable revenue represented approximately 94% of total ePlex product revenue during the three months ended March 31, 2019. XT-8 revenue decreased by $2.9 million to $5.7 million during the three months ended March 31, 2019 primarily due to customers converting to our ePlex system for respiratory testing.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Cost of revenue	$15,670	$16,480	$ (810)	(5)%
Gross profit	$5,863	$4,165	$ 1,698	41 %

The decrease in cost of revenue for the three months ended March 31, 2019, compared to the same period of the prior year, is primarily attributable to improvements related to manufacturing yields, overhead absorption, and reductions in material costs. These decreases to costs of revenue during the three months ended March 31, 2019 totaled $1.5 million from manufacturing efficiencies and $780 thousand from product technical support costs as compared to the same period in the prior year. These decreases were partially offset by an increase in gross product costs of $1.1 million attributed to the increase in ePlex product sales, which carries a higher cost profile due to its enhanced technology and features, as compared to XT-8. In addition, inventory reserves increased by $163 thousand when comparing the three months ended March 31, 2019 to the same period of the prior year.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Sales and marketing	$5,909	$5,402	$ 507	9 %

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The increase in sales and marketing expense for the three months ended March 31, 2019, when compared to the same period of the prior year, was primarily driven by increases in evaluation kit expense of $273 thousand resulting from new ePlex system implementations and $106 thousand in sales commissions driven by increased revenue.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
General and administrative	$4,521	$4,133	$ 388	9 %

The increase in general and administrative expense for the three months ended March 31, 2019, compared to the same period of the prior year, was primarily driven by increases in employee-related expenses of $150 thousand and $190 thousand in higher facilities and information technology expense.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Research and development	$6,343	$5,420	$ 923	17 %

The increase in research and development expense for the three months ended March 31, 2019, compared to the same period of the prior year, was primarily driven by increases of $595 thousand in prototype materials used by our assay development teams, $611 thousand in personnel costs based upon more technical resources focused on the development of future technologies, and $101 thousand in laboratory supplies. These increases were partially offset by a $410 thousand decline in clinical study expense in the current period based upon the timing of the completed ePlex BCID clinical studies.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Other income (expense)	$(1,154)	$(613)	$ (541)	88 %

Other income (expense) represents non-operating income and expense, including, but not limited to, earnings on cash, cash equivalents, restricted cash, marketable securities, foreign exchange gains and losses of foreign currency denominated balances, and interest expense related to debt.

The change in other income (expense) for the three months ended March 31, 2019, compared to the same period of the prior year, was primarily due to higher interest expense attributable to additional borrowings from the Company's new loan and security agreement.

	Three Months Ended March 31,			
	2019	2018	$ Change	% Change
	(dollars in thousands)			
Income tax expense (benefit)	$16	$20	$ (4)	(20)%

Due to net losses incurred, we have only recorded tax provisions related to minimum tax payments in the United States and tax liabilities generated by our foreign subsidiaries, which have remained immaterial.

Liquidity and Capital Resources

To date, we have funded our operations primarily from the sale of our common stock, borrowings, and cash from operations. We have incurred net losses from continuing operations each year and have not yet achieved profitability. As of March 31, 2019, we had $51,896,000 of working capital, including $48,422,000 in cash, cash equivalents, and marketable securities. We believe our existing cash, cash equivalents and marketable securities as of March 31, 2019 will enable us to fund our operations for at least the next 12 months.

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

Three Months Ended (in thousands):	March 31, 2019			2018		
Net cash used in operating activities	$	(8,181	)	$	(6,052	)
Net cash provided by (used in) investing activities	(4,547		)	9,635		
Net cash provided by (used in) financing activities	11,726			(25		)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	20			(34		)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$	(982	)	$	3,524	

Cash used in operating activities
Net cash used in operating activities increased $2.1 million for the three months ended March 31, 2019 compared to the same period of the prior year. The increase in cash used in operating activities was primarily due to an increase of $0.7 million in net loss and a decrease of $1.5 million in changes to operating assets and liabilities; partially offset by an increase of $0.1 million in non-cash adjustments.

Cash provided by (used in) investing activities
Net cash used in investing activities increased by $14.2 million for the three months ended March 31, 2019, compared to the same period of the prior year, primarily due to a decrease in the net proceeds from purchases, maturities, and sales of marketable securities of $14.3 million, partially offset by a decline in purchases of property and equipment of $132 thousand.

Cash provided by (used in) financing activities
Net cash provided by financing activities increased by $11.8 million for the three months ended March 31, 2019, compared to the same period of the prior year, primarily due to an increase in proceeds from borrowings of $11.3 million and an increase in stock option exercises of $413 thousand.

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

• the level of revenues and the rate of our revenue growth;
• change in demand from our customers;
• the level of expenses required to expand our commercial (sales and marketing) activities;

- change in demand from our customers;
- the level of research and development investment required to develop and commercialize our ePlex system and maintain our XT-8 system;
- the level of investment required to scale our manufacturing operations to support our anticipated growth;
- 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

On February 1, 2019, or the Effective Date, we entered into a Loan and Security Agreement, or the New LSA, with Solar Capital Ltd. and certain other financial institutions, or, collectively, the Lenders. Pursuant to the New LSA, the Lenders are providing us with up to $65 million in a series of term loans, of which $50 million was funded on the Effective Date. We may borrow an additional $15 million at our option, but no later than December 31, 2019, provided that we achieve a designated amount of product revenues on a trailing six-month basis. As of March 31, 2019, we have borrowed $50 million under the terms of the New LSA.

Pursuant to the terms of the New LSA, 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, and (b) the stock of all of our subsidiaries; provided that if the pledge of 100% of the voting shares of our non-U.S. subsidiaries would result in adverse tax consequences, such pledge shall be limited to 65% of the voting stock and 100% of the non-voting stock of each of our non-U.S. subsidiaries.

The New LSA 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 New LSA. The New LSA also contains customary events of default (subject, in certain instances, to specified cure periods), including, but not limited to, the failure to make payments of interest or premium when due, the failure to comply with certain covenants and agreements specified in the New LSA, and the occurrence of a material adverse change, certain regulatory events, or certain insolvency events. Upon the occurrence of an event of default, the Lenders may declare all outstanding principal and accrued but unpaid interest under the LSA immediately due and payable and may exercise the other rights and remedies as set forth in the New LSA.

Letter of Credit

In September 2012, we provided a $758,000 letter of credit issued by Banc of California to the landlord of our executive office facility in Carlsbad, California. This letter of credit was secured with $758,000 of restricted cash at March 31, 2019.

If we require additional capital, 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

As of March 31, 2019, there were no material changes to our contractual obligations from those disclosed within the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

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 certain 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 intangible assets 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, 2018. There have been no material changes to our critical accounting policies and estimates during the three months ended March 31, 2019.

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 executive office facility in Carlsbad, California, which is recorded as restricted cash on our unaudited condensed consolidated balance sheets.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At March 31, 2019, there have been no material changes in our market risks described at December 31, 2018.

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

Interest Rate Risk

As of March 31, 2019, based on current interest rates and total borrowings outstanding, a hypothetical 100 basis point increase or decrease in interest rates would have an immaterial pre-tax impact on our results of operations.

Foreign Currency Exchange Risks

We are a U.S. entity and our functional currency is the U.S. dollar. We have business transactions in foreign currencies, however, we believe we do not have significant exposure to risk from changes in foreign currency exchange rates at this time. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

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, 2019, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

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

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PART II. OTHER INFORMATION
ITEM 1. LEGAL PROCEEDINGS

We are from time to time subject to various claims and legal actions in the ordinary course of our business. We believe that there are currently no 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, 2019. 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, 2018.

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

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 August 2, 2018).
10.1*	The GenMark Diagnostics 2019 Bonus Plan (incorporated by reference to our Current Report on Form 8-K filed with the SEC on February 21, 2019).
10.2+	Loan and Security Agreement dated February 1, 2019 by and among GenMark Diagnostics, Inc. and its domestic subsidiaries, as co-borrowers, and Solar Capital Ltd. and the financial institutions that are or become parties to the Agreement, as Lenders.
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.

* Indicates a management contract or compensatory plan or arrangement in which any director or named executive officer participates.

+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

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:	April 30, 2019	By:	/s/ HANY MASSARANY Hany Massarany President and Chief Executive Officer (Principal Executive Officer)
Date:	April 30, 2019	By:	/s/ JOHNNY EK Johnny Ek Chief Financial Officer (Principal Financial and Accounting Officer)