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 September 30, 2018

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 Carlsbad, California	**92008-8829**
(Address of principal executive offices)	**(Zip code)**

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

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

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, 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	☒
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 ☒

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 October 25, 2018, was 55,955,284.

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)

	September 30, 2018	December 31, 2017
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 25,005	$ 26,754
Short-term marketable securities	17,657	45,236
Accounts receivable, net of allowances of $75 and $2,754, respectively	9,858	10,676
Inventories	11,254	10,949
Prepaid expenses and other current assets	1,894	2,216
Total current assets	65,668	95,831
Property and equipment, net	21,873	22,581
Intangible assets, net	2,170	2,624
Restricted cash	758	758
Other long-term assets	562	505
Total assets	$ 91,031	$ 122,299
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 8,242	$ 11,171
Accrued compensation	6,987	5,419
Current portion of long-term debt	—	7,927
Other current liabilities	2,302	3,226
Total current liabilities	17,531	27,743
Deferred rent	2,952	3,059
Long-term debt	28,730	20,099
Other noncurrent liabilities	112	241
Total liabilities	49,325	51,142
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 55,955 and 55,066 shares issued and outstanding, respectively	6	6
Additional paid-in capital	497,018	487,525
Accumulated deficit	(455,322)	(416,383)
Accumulated other comprehensive income	4	9
Total stockholders’ equity	41,706	71,157
Total liabilities and stockholders’ equity	$ 91,031	$ 122,299

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 September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue:				
Product revenue	$ 15,713	$ 11,552	$ 51,156	$ 36,313
License and other revenue	82	51	225	184
Total revenue	15,795	11,603	51,381	36,497
Cost of revenue	10,165	7,400	37,172	21,227
Gross profit	5,630	4,203	14,209	15,270
Operating expenses:				
Sales and marketing	5,375	5,121	15,964	14,974
General and administrative	4,718	3,565	13,398	11,553
Research and development	6,105	10,248	22,007	34,297
Total operating expenses	16,198	18,934	51,369	60,824
Loss from operations	(10,568)	(14,731)	(37,160)	(45,554)
Other income (expense):				
Interest income	188	247	577	353
Interest expense	(661)	(1,009)	(2,246)	(2,270)
Other income (expense)	53	76	(49)	227
Total other income (expense)	(420)	(686)	(1,718)	(1,690)
Loss before provision for income taxes	(10,988)	(15,417)	(38,878)	(47,244)
Income tax expense (benefit)	5	(9)	59	68
Net loss	$ (10,993)	$ (15,408)	$ (38,937)	$ (47,312)
Net loss per share, basic and diluted	$ (0.20)	$ (0.28)	$ (0.70)	$ (0.95)
Weighted average number of shares outstanding, basic and diluted	55,847	54,726	55,535	49,908
Other comprehensive loss:				
Net loss	$ (10,993)	$ (15,408)	$ (38,937)	$ (47,312)
Other comprehensive income/(loss):				
Foreign currency translation adjustments, net of tax	49	51	29	145
Net unrealized gains (losses) on marketable securities, net of tax	4	(9)	26	(24)
Total other comprehensive income/(loss)	53	42	55	121
Total comprehensive loss	$ (10,940)	$ (15,366)	$ (38,882)	$ (47,191)

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Operating activities:		
Net loss	$ (38,937)	$ (47,312)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,281	3,811
Net amortization/(accretion) of premiums/discounts on investments	(110)	4
Amortization of deferred debt issuance costs	725	891
Stock-based compensation	8,895	8,386
Provision for bad debt	24	51
Non-cash inventory adjustments	1,061	911
Other non-cash adjustments	(62)	(190)
Changes in operating assets and liabilities:		
Accounts receivable	797	1,272
Inventories	(3,847)	(4,813)
Prepaid expenses and other assets	384	(767)
Other long-term assets	—	(16)
Accounts payable	(3,408)	(1,468)
Accrued compensation	1,053	(452)
Other current and non-current liabilities	(756)	(913)
Net cash used in operating activities	(28,900)	(40,605)
Investing activities:		
Payments for intellectual property licenses	—	(500)
Purchases of property and equipment, net	(1,060)	(3,816)
Purchases of marketable securities	(28,785)	(56,525)
Proceeds from sales of marketable securities	—	13,896
Maturities of marketable securities	56,500	8,500
Net cash provided by (used in) investing activities	26,655	(38,445)
Financing activities:		
Proceeds from issuance of common stock	535	86,835
Costs incurred in conjunction with public offering	—	(5,469)
Principal repayment of borrowings	(68)	(6,123)
Proceeds from borrowings	—	15,000
Payments associated with debt issuance	(20)	(187)
Proceeds from stock option exercises	22	213
Net cash provided by financing activities	469	90,269
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	27	(17)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(1,749)	11,202
Cash, cash equivalents, and restricted cash at beginning of year	27,512	16,717
Cash, cash equivalents, and restricted cash at end of period	$ 25,763	$ 27,919
Non-cash investing and financing activities:		
Transfer of systems (from) to property and equipment into (from) inventory	$ 2,477	$ (3,438)
Property and equipment included in accounts payable	$ 746	$ 330
Intellectual property acquisitions included in other current liabilities	$ —	$ —
Supplemental cash flow information:		
Cash paid for income taxes, net	$ 133	$ 58
Cash paid for interest	$ 1,517	$ 1,143

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 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 automated, multiplex molecular diagnostic testing systems that detect and measure DNA and RNA targets to diagnose disease and optimize patient treatment.

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, 2017 filed with the SEC on February 27, 2018. 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 $455,322,000 as of September 30, 2018. 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 September 30, 2018, the Company had available cash, cash equivalents, and marketable securities of $42,662,000 and working capital of $48,137,000 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, 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 the new standard in the second quarter of 2018 and determined that the application of the new standard did not have a material impact on the Company's unaudited condensed consolidated financial statements.

In November 2016, the FASB issued ASU, 2016-18, *Statement of Cash Flows (Topic 230) Restricted Cash*, which requires amounts generally described as restricted cash and restricted cash equivalents to be included in the cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 (including interim periods within those periods) using a retrospective transition method for each period presented, with early adoption permitted. The Company adopted the new standard in the first quarter of 2018 using the retrospective transition method resulting in an increase in the beginning and ending cash balance of $758,000 for each period presented.

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 assets for all leases with lease terms of greater than 12 months. It 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 will be effective for the Company starting in the first quarter of 2019, with early adoption permitted. The Company believes that adoption of this guidance will modify its analysis and disclosures of lease agreements because operating agreements are a significant portion of the Company's total lease commitments. The Company intends to adopt this guidance in the first quarter of 2019 and is in the process of determining the effects the adoption of this guidance will have on its unaudited condensed consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606),* an updated standard on revenue recognition. The new standard provides enhancements to the quality and consistency of how revenue is reported under the principle that revenue should be recognized in an amount that reflects the consideration to which the Company expects to be entitled in exchange for the transfer of promised goods or services. The Company adopted the new standard using the modified retrospective transition method. The cumulative effect of applying the new standard as of January 1, 2018 resulted in a net increase in opening retained earnings of $736,000 to capitalize certain costs to obtain sales contracts. The Company recognized $400,000 in expense related to the amortization of capitalized contract costs during the nine months ended September 30, 2018. Aside from this adjustment to beginning retained earnings and the related amortization of expense during the nine months ended September 30, 2018, the application of this standard did not have a material impact on the Company's unaudited condensed consolidated financial statements as of and for the nine months ended September 30, 2018.

Revenue

The Company recognizes revenue from operations through the sale of products and other services. Product revenue is comprised of 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue Source:				
ePlex product revenue	$ 6,743	$ 2,311	$ 25,757	$ 4,385
XT-8 product revenue	8,970	9,241	25,399	31,928
Total product revenue	15,713	11,552	51,156	36,313
License and other revenue	82	51	225	184
Total revenue	$ 15,795	$ 11,603	$ 51,381	$ 36,497

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 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 September 30, 2018 and December 31, 2017, 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

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 computations of diluted net loss per share for the three and nine month periods ended September 30, 2018 and 2017 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Options outstanding to purchase common stock	2,445	2,526	2,445	2,526
Other unvested equity awards	3,466	2,466	3,466	2,466
Total	5,911	4,992	5,911	4,992

3. 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, 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 nine months ended September 30, 2018 and 2017, aggregate stock-based compensation expense was $8,895,000 and $8,386,000, 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 nine months ended September 30, 2018:

	Number of Shares		Weighted Average Exercise Price
Outstanding at December 31, 2017	2,490,465	$	9.59
Granted	—	$	—
Exercised	(5,042)	$	4.33
Cancelled	(40,153)	$	11.20
Outstanding at September 30, 2018	2,445,270	$	9.58
Vested and expected to vest at September 30, 2018	2,443,432	$	9.58
Exercisable at September 30, 2018	2,383,339	$	9.49

Options that were exercisable as of September 30, 2018 had a remaining weighted average contractual term of 4.38 years, and an aggregate intrinsic value of $1,729,000. As of September 30, 2018, there were 2,445,270 stock options outstanding, which had a remaining weighted average contractual term of 4.43 years and an aggregate intrinsic value of $1,734,000. No stock options were granted during the nine months ended September 30, 2018.

Restricted Stock Awards and Units

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. In March 2013, the Company transitioned to granting restricted stock units under the 2010 Plan in lieu of granting restricted stock awards.

Restricted stock awards or units granted under the 2010 Plan generally vest over a period of between one and four years and are typically forfeited if employment is terminated before the restricted stock awards or units vest. The compensation expense related to the restricted stock awards or 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 nine months ended September 30, 2018 and 2017 was as follows:

	Restricted Stock Units		
	Number of Shares		Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	2,073,440	$	9.14
Granted	1,726,126	$	4.51
Vested	(750,310)	$	9.54
Cancelled	(137,308)	$	8.83
Unvested at September 30, 2018	2,911,948	$	6.30

As of September 30, 2018, there was $12,780,000 of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.58 years. The total fair value of restricted stock units that vested during the nine months ended September 30, 2018 and 2017 was $4,392,000 and $4,181,000, respectively.

Market-Based Stock Units

The Company issued market-based stock units in February 2018, 2017, and 2016, 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 September 30, 2018, there was $1,451,000 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 1.53 years.

The Company’s market-based stock unit activity for the nine months ended September 30, 2018 was as follows:

	Market-Based Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2017	233,743	$ 10.88
Target units granted	320,000	$ 7.19
Unvested at September 30, 2018	553,743	$ 8.75

The fair value of these market-based stock units was estimated on the date of grant 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 nine months ended September 30, 2018:

	Nine Months Ended September 30,	
	2018	2017
Expected volatility	65%	54%
Risk-free interest rate	2.40%	1.50%
Expected dividend	—%	—%
Weighted average fair value	$ 7.19	$ 13.82

Employee Stock Purchase Plan

The Company's stockholders approved the ESPP in May 2013. 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. In March 2018, the Company’s Board of Directors approved the amendment and restatement of the ESPP to increase the total number of shares authorized for issuance under the ESPP from 650,000 shares to 1,750,000 shares, which was approved by the Company’s stockholders at the Company’s 2018 Annual Stockholder Meeting held on May 24, 2018.

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 September 30, 2018, there were 1,059,213 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 the nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of revenue	$ 230	$ 124	$ 637	$ 398
Sales and marketing	719	703	2,059	2,061
Research and development	605	693	1,890	2,121
General and administrative	1,542	1,264	4,309	3,806
Total stock-based compensation expense	$ 3,096	$ 2,784	$ 8,895	$ 8,386

Stock-based compensation capitalized during the periods presented was not material and there was no unrecognized tax benefit related to stock-based compensation for the nine months ended September 30, 2018 and 2017.

4. Condensed Consolidated Financial Statement Details

The following tables show the Company's unaudited condensed consolidated financial statement details as of September 30, 2018 and December 31, 2017 (in thousands):

Inventory

	September 30, 2018	December 31, 2017
Raw materials	$ 2,805	$ 4,534
Work-in-process	4,037	3,638
Finished goods	4,412	2,777
Total inventories	$ 11,254	$ 10,949

Property and Equipment, Net

	September 30, 2018	December 31, 2017
Property and equipment — at cost:		
Machinery and laboratory equipment	$ 15,296	$ 13,762
Instruments	14,778	13,347
Office equipment	2,146	1,948
Leasehold improvements	10,612	10,480
Total property and equipment — at cost	42,832	39,537
Less: accumulated depreciation	(20,959)	(16,956)
Property and equipment, net	$ 21,873	$ 22,581

Accrued Warranty

The following table shows changes in the Company's accrued warranties for the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Beginning accrued warranty balance	$ 439	$ 253	$ 470	$ 219
Warranty expenses incurred	(148)	(126)	(1,222)	(675)
Provisions	84	189	1,127	772
Ending accrued warranty balance	$ 375	$ 316	$ 375	$ 316

5. Intangible Assets, net

Intangible assets as of September 30, 2018 and December 31, 2017 comprised the following (in thousands):

	September 30, 2018			December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Licensed intellectual property	$ 4,750	$ (2,580)	$ 2,170	$ 4,750	$ (2,126)	$ 2,624

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. During the nine months ended September 30, 2017, the Company satisfied certain commercial milestones under this agreement requiring a payment of $500,000 recorded as an addition to licensed intellectual property.

Intellectual property licenses have a weighted average remaining amortization period of 3.68 years as of September 30, 2018. Amortization expense for these licenses was $156,000 and $151,000 for the three months ended September 30, 2018 and 2017, respectively, and was $453,000 and $398,000 for the nine months ended September 30, 2018 and 2017, respectively. Estimated future amortization expense for these licenses is as follows (in thousands):

Fiscal Years Ending	Future Amortization Expense
Remaining in 2018	$ 139
2019	593
2020	593
2021	593
2022	252
Total	$ 2,170

6. Marketable Securities

The following table summarizes the Company's marketable securities as of September 30, 2018 and December 31, 2017 (in thousands):

September 30, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 11,386	$ —	$ (4)	$ 11,382
U.S. government and agency securities	3,494	—	(1)	3,493
Commercial paper	2,782	—	—	2,782
Total	$ 17,662	$ —	$ (5)	$ 17,657

December 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds	$ 26,303	$ —	$ (25)	$ 26,278
U.S. government and agency securities	11,981	—	(5)	11,976
Commercial paper	6,982	—	—	6,982
Total	$ 45,266	$ —	$ (30)	$ 45,236

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 September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 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	$ 9,986	$ —	$ —	$ 9,986
Marketable securities				
Corporate notes and bonds	—	11,382	—	11,382
U.S. government and agency securities	—	3,493	—	3,493
Commercial paper	—	2,782	—	2,782
Total	$ 9,986	$ 17,657	$ —	$ 27,643

	December 31, 2017			
	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	$ 6,362	$ —	$ —	$ 6,362
Corporate notes and bonds	—	1,498	—	1,498
Marketable securities				
Corporate notes and bonds	—	26,278	—	26,278
U.S. government and agency securities	—	11,976	—	11,976
Commercial paper	—	6,982	—	6,982
Total	$ 6,362	$ 46,734	$ —	$ 53,096

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 September 30, 2018 and December 31, 2017, long-term debt consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Term Loans		
Term Loan A - $10.0 million at 6.9% interest	$ 7,619	$ 7,619
Term Loan B - $10.0 million at 6.9% interest	7,619	7,619
Term Loan C - $15.0 million at 7.4% interest	12,000	12,000
Term Loan D - $0.7 million at 8.8% interest	663	—
Final fee obligation	2,632	2,429
Unamortized issuance costs	(1,803)	(1,641)
Total debt, net	28,730	28,026
Current portion of long-term debt	—	(7,927)
Long-term debt	$ 28,730	$ 20,099

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, or the 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. The term loans accrue 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.

On September 28, 2018, the Company entered into a sixth amendment, or the Amendment, to its LSA. Pursuant to the Amendment, the Company and its Lenders agreed to extend the interest-only period in respect of amounts borrowed by the Company under the Agreement until January 1, 2020. The parties also agreed to extend the final maturity date on which all of the Company's loans, debts, obligations and other liabilities under the Agreement become due until January 1, 2021, or the Final Maturity Date. In addition, the Amendment provides that outstanding principal and interest payments made by the Company to the Lenders between January 1, 2020 and the Final Maturity Date will be calculated on a 24-month amortization schedule, and that the Company will be required to make the final payment of all remaining outstanding principal and interest accrued thereon on the Final Maturity Date.

Pursuant to the terms of the Amendment, the Lenders agreed to reallocate the Company's borrowings under the Agreement among the Lenders and one Lender, or the Former Lender, was repaid in full their pro rata portion of the outstanding principal and interest borrowed by the Company under the Agreement. In connection with the Former Lender's repayment, approximately $663,000 in additional principal was added to the Company's borrowings pursuant to a new term loan made available under the Agreement, which amount was immediately used to pay the pro-rata portion of the final fee due to the Former Lender. As of September 30, 2018, the Company had borrowed all $35,663,000 under the term loans as provided in the LSA, and the Company had not borrowed any of the $5,000,000 available under the revolving loan.

The Company will be required to pay a $20 thousand annual management fee due on each anniversary of the closing date of the Amendment and a $2.6 million final payment fee due on the Final Maturity Date. The Amendment was accounted for as a debt modification with the issuance costs and fees of the term loans being amortized over the revised term of the LSA.

Under the 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 LSA. As of September 30, 2018, the Company was in compliance with all covenants under the LSA.

Revolving Loan

Pursuant to the LSA, the Company may borrow up to $5,000,000 under a 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 LSA. All principal and interest outstanding under the revolving loan is due and payable on the Final Maturity Date. 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 September 30, 2018, the Company had not borrowed any amounts pursuant the revolving loan facility.

Debt Issuance Costs

As of September 30, 2018 and December 31, 2017, the Company had $1,803,000 and $1,641,000, respectively, of unamortized debt issuance discount, which is offset against borrowings in long-term and short-term debt.

Amortization of debt issuance costs was $142,000 and $398,000 for the three months ended September 30, 2018 and 2017, respectively, and was $725,000 and $891,000 for the nine months ended September 30, 2018 and 2017, 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 September 30, 2018.

9. Leases

The Company has operating and capital lease agreements for its office, manufacturing, warehousing and laboratory space and for office equipment. Rent and operating expenses charged under these arrangements was $485,000 and $399,000 for the three months ended September 30, 2018 and 2017, respectively, and was $1,355,000 and $1,211,000 for the nine months ended September 30, 2018 and 2017, respectively. Pursuant to the Company's lease agreements, a portion of the monthly rent has been deferred. The balance of deferred rent as of September 30, 2018 and December 31, 2017 was $3,373,000 and $3,652,000, respectively.

In July 2018, the Company entered into an amendment to the existing lease for its corporate headquarters, which extended the term of the lease by an additional four years through June 2025. Base rent adjusts periodically throughout the extended term of this lease with monthly lease payments ranging from $107,000 to $117,000. The Company also received certain abatements to their rent during the three and nine months ended September 30, 2018.

As of September 30, 2018, 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 2018	$ 227
2019	1,989
2020	1,997
2021	2,015
2022	2,077
Thereafter	4,023
Total	$ 12,328

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 September 30, 2018, 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 (benefit) of $5,000 and $(9,000) for the three months ended September 30, 2018 and 2017, and income tax expense of $59,000 and $68,000 for the nine months ended September 30, 2018 and 2017, respectively.

The Company continues to monitor guidance issued by the U.S. Treasury Department, the Internal Revenue Service, and other standard-setting bodies related to the Tax Cuts and Jobs Act, or the Jobs Act, enacted in 2017. Due to the timing of the enactment and the complexity involved in applying the provisions of the Jobs Act, the Company made reasonable estimates of the effects and recorded provisional amounts in the consolidated financial statements as of December 31, 2017. No adjustments were made to the provisional amounts recorded related to the Jobs Act during the nine months ended September 30, 2018. The Company expects to complete the accounting for tax effects of the Jobs Act in fiscal year 2018.

The Company is subject to taxation in the United States and in various state and foreign jurisdictions. The Company's federal and state returns since inception are subject to examination due to the carryover of net operating losses. As of September 30, 2018, 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 nine months ended September 30, 2018 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, 2017.

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 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 molecular tests that aid in the diagnosis of complex medical conditions and help guide therapy decisions. 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 nine months ended September 30, 2018 and 2017 were approximately $38,937,000 and $47,312,000, respectively. As of September 30, 2018, we had an accumulated deficit of $455,322,000. 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 sample-to-answer ePlex instrument and Respiratory Pathogen (RP) Panel for sale in the United States and Europe. We have also obtained CE Mark for our ePlex BCID-GP Panel, ePlex BCID-GN Panel, and ePlex BCID-FP Panel. We submitted a 510(k) application to the FDA for our ePlex BCID-GP Panel in June 2018, and submitted 510(k) applications for our ePlex BCID-GN Panel and ePlex BCID-FP Panel to the FDA in September 2018. 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.

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 have also developed a number of hepatitis C virus, or HCV, genotyping tests and custom manufactured reagents, as well as other research-based and pharmacogenomics products, versions of which are available for use with our XT-8 instrument for research use only (RUO).

Revenue

We recognize revenue from operations through the sale of our products and other services. Product revenue is comprised of 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 we expect to receive from the customer in exchange for those products and services.

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. We manufacture our test cartridges in our facilities and have recently invested in significant capacity for expansion. 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 tests; 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, instrument 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 of our ePlex instrument and its expanding 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, 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.

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 and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	2017	$ Change	% Change	2018	2017	$ Change	% Change
	(dollars in thousands)				*(dollars in thousands)*			
Revenue	$ 15,795	$ 11,603	$ 4,192	36%	$ 51,381	$ 36,497	$ 14,884	41%

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 $4.2 million, or 36%, for the three months ended September 30, 2018 when compared to the same period of the prior year, primarily driven by growth in ePlex product revenue relative to XT-8 product revenue. The increase in revenue generated by ePlex sales in the US and further expansion of the ePlex system internationally reflects increased units sold at a higher selling price driven by the additional technology and features of its sample-to-answer capabilities as compared to the XT-8 system. Revenue from consumable sales increased to $14.7 million for the three months ended September 30, 2018 compared to $10 million for the same period in the prior year. Instrument sales decreased by $575 thousand during the three months ended September 30, 2018 when compared to the same period of the prior year. Pricing changes did not have a material impact on revenue during the three months ended September 30, 2018.

The increase in revenue for the nine months ended September 30, 2018 when compared to the same period of the prior year was primarily driven by an increase in ePlex sales in the U.S. and the further expansion of the ePlex system internationally. Revenue from consumable sales increased to $48.3 million for the nine months ended September 30, 2018 compared to $33.5 million for the same period in the prior year. Instrument sales decreased by $23 thousand during the nine months ended September 30, 2018 when compared to the same period of the prior year. Pricing changes did not have a material impact on revenue during the nine months ended September 30, 2018.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	2017	$ Change	% Change	2018	2017	$ Change	% Change
	(dollars in thousands)				*(dollars in thousands)*			
Cost of revenue	$ 10,165	$ 7,400	$ 2,765	37%	$ 37,172	$ 21,227	$ 15,945	75 %
Gross profit	$ 5,630	$ 4,203	$ 1,427	34%	$ 14,209	$ 15,270	$ (1,061)	(7)%

The increase in cost of revenue for the three months ended September 30, 2018, compared to the same period of the prior year, was primarily related to higher overall product revenue and specifically, the growth in ePlex product revenue relative to XT-8 product revenue. The cost profile of the ePlex platform reflects the additional technology and features of its sample-to-answer capabilities coupled with it being early in its product life cycle. Increases in our cost of revenue were attributable to product costs of $3.7 million corresponding to volume increases and the increase in ePlex sales in addition to increased overhead and consumable warranty expenses of $237 thousand. These increases were partially offset by a decrease in product support expense of $530 thousand, improved manufacturing efficiencies of $380 thousand, and a decrease in inventory reserves, warranty and repairs, and royalties expense of $187 thousand. The increase in gross profit of $1.4 million was primarily due to increased product sales.

The increase in cost of revenue for the nine months ended September 30, 2018, compared to the same period of the prior year, was primarily related to higher product revenue following the ramp up of the commercialization of the ePlex platform in the current period. Increases in our cost of revenue were attributable to product costs of $14.3 million corresponding to volume increases and specifically, increases in ePlex product revenue, decreased production efficiencies of $1 million, increased instrument depreciation, warranty and repair expense of $272 thousand, increased inventory reserve expense of $286 thousand, increased consumable warranty expense of $187 thousand, as well as increased freight out expense of $118 thousand. These increases were partially offset by decreases in royalty expense of $127 thousand and product support expenses of $95 thousand. The decrease in gross profit of $1.1 million was primarily due to a higher composition of ePlex product revenue as compared to XT-8 product revenue.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	**2017**	**$ Change**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**
	(dollars in thousands)				*(dollars in thousands)*			
Sales and marketing	$ 5,375	$ 5,121	$ 254	5%	$ 15,964	$ 14,974	$ 990	7%

The increase in sales and marketing expense for the three months ended September 30, 2018, when compared to the same period of the prior year, was primarily driven by an increase in facility and depreciation expense of $73 thousand associated with additional placements of ePlex systems, an increase of $163 thousand in sample consumable expense, an increase of $129 thousand in supplies expense, partially offset by a decrease in other marketing, professional services, and employee-related expenses of $95 thousand.

The increase in sales and marketing expense for the nine months ended September 30, 2018, when compared to the same period of the prior year, was primarily driven by increases in sample consumable expense of $485 thousand, facility and depreciation expense of $296 thousand, employee-related expenses and professional services of $195 thousand, and supplies expense of $113 thousand, partially offset by a decrease in other marketing expense of $121 thousand.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	**2017**	**$ Change**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**
	(dollars in thousands)				*(dollars in thousands)*			
General and administrative	$ 4,718	$ 3,565	$ 1,153	32%	$ 13,398	$ 11,553	$ 1,845	16%

The increase in general and administrative expense for the three months ended September 30, 2018, compared to the same period of the prior year, was primarily driven by an increase in employee-related expenses of $1 million, including a $278 thousand increase in stock-based compensation expense and lower 2017 incentive compensation of $214 thousand consistent with a revision to the Company's business performance expectations, and an increase in professional services expense of $142 thousand.

The increase in general and administrative expense for the nine months ended September 30, 2018, compared to the same period of the prior year, was primarily driven by increases in employee-related expenses of $1.3 million, including $489 thousand in stock-based compensation expense, and professional services expense of $619 thousand, partially offset by a decrease of $69 thousand in maintenance expense.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	**2017**	**$ Change**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**
	(dollars in thousands)				*(dollars in thousands)*			
Research and development	$ 6,105	$ 10,248	$ (4,143)	(40)%	$ 22,007	$ 34,297	$ (12,290)	(36)%

The decrease in research and development expense for the three months ended September 30, 2018, compared to the same period of the prior year, was primarily driven by a decrease of $4.6 million in supplies and prototype materials used by our assay development teams partially offset by an increase in clinical study expense of $226 thousand due to the timing of the recently completed ePlex BCID clinical studies, and an increase in employee-related expenses of $185 thousand.

The decrease in research and development expense for the nine months ended September 30, 2018, compared to the same period of the prior year, was primarily driven by a decrease in ePlex instrument development expenses of $11.9 million and a decrease in employee-related expenses of $1.4 million, partially offset by an increase in clinical study expense of $863 thousand due to the timing of the ePlex BCID clinical studies, and an increase in facility and depreciation expense of $132 thousand.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	**2017**	**$ Change**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**
	(dollars in thousands)				*(dollars in thousands)*			
Other income (expense)	$ (420)	$ (686)	$ (266)	39%	$ (1,718)	$ (1,690)	$ 28	(2)%

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 September 30, 2018, compared to the same period of the prior year, was primarily due to a decrease in interest expense of $347 thousand on amounts due under our loan and security agreement, partially offset by a decline in interest income from short-term marketable securities of $59 thousand.

The change in other income (expense) for the nine months ended September 30, 2018, compared to the same period of the prior year, was primarily due to changes in foreign currencies of $278 thousand, partially offset by a decrease in interest income from short-term marketable securities of $224 thousand, and a decrease in interest expense of $24 thousand on amounts due under our loan and security agreement.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2018	**2017**	**$ Change**	**% Change**	**2018**	**2017**	**$ Change**	**% Change**
	(dollars in thousands)				*(dollars in thousands)*			
Income tax expense (benefit)	$ 5	$ (9)	$ 14	(156)%	$ 59	$ 68	$ (9)	(13)%

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 September 30, 2018, we had $48,137,000 of working capital, including $42,662,000 in cash, cash equivalents, and marketable securities. We believe our existing cash, cash equivalents and marketable securities as of September 30, 2018 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:

	September 30,	
Nine Months Ended (in thousands):	**2018**	**2017**
Net cash used in operating activities	$ (28,900)	$ (40,605)
Net cash provided by (used in) investing activities	26,655	(38,445)
Net cash provided by financing activities	469	90,269
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	27	(17)
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (1,749)	$ 11,202

Cash flows used in operating activities

Net cash used in operating activities decreased $11,705,000 for the nine months ended September 30, 2018 compared to the same period of the prior year. The decrease in cash used in operating activities was primarily due to decreases of $1,380,000 from changes in operating assets and liabilities resulting from increases in prepaid expenses and other assets, accrued compensation, and inventories, partially offset by decreases in accounts payable and accounts receivable. Cash used in operating activities also decreased as a result of $8,375,000 in net loss and $1,950,000 in non-cash adjustments resulting from increased depreciation and amortization, stock-based compensation, and inventory reserves.

Cash flows provided by (used in) investing activities

Net cash provided by investing activities increased by $65,100,000 for the nine months ended September 30, 2018, compared to the same period of the prior year, primarily due to an increase in net proceeds from purchases, maturities, and sales of marketable securities of $61,844,000 and a decrease in purchases of property and equipment of $3,256,000.

Cash flows provided by financing activities

Net cash provided by financing activities decreased by $89,800,000 for the nine months ended September 30, 2018, compared to the same period of the prior year, primarily due to decreases in the proceeds from the sale of common stock (net of issuance costs) of $80,831,000, a decrease in the proceeds from borrowings (net of issuance costs) of $14,833,000, and stock option exercises of $191,000, partially offset by a decrease in principal payments on borrowings of $6,055,000.

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

In January 2015, we 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, pursuant to which we originally obtained $35,000,000 in a series of term loans and a revolving loan in the maximum amount of $5,000,000. Pursuant to the terms of the sixth amendment to its LSA, the Company borrowed an additional $663,000 to repay the pro rata portion of the outstanding principal and interest due to one lender.

As of September 30, 2018, we borrowed all $35,663,000 under the terms loans as provided in the LSA and had not borrowed any of the $5,000,000 available under the revolving loan.

Pursuant to the terms of the 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, (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 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 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 September 30, 2018.

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 September 30, 2018, 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, 2017.

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, 2017. There have been no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2018.

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 September 30, 2018, there have been no material changes in our market risks described at December 31, 2017.

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 September 30, 2018, 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 September 30, 2018, 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.

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

You should consider the risks described below and all of the other information set forth in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in evaluating our business and prospects. If any of the risks described below occurs, our business, financial condition or results of operations could be negatively affected. In that case, the market price of our common stock could decline.

We have marked with an asterisk (*) those risks described below that reflect new risks or substantive changes from the risks described under Part I, Item 1A "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2017.

We may not successfully commercialize our ePlex system at the levels we anticipate.

Our current plan for achieving positive cash flow and our future growth projections relies upon the successful commercialization of our ePlex system at the levels we project. Our ePlex system integrates automated nucleic acid extraction and amplification with our eSensor technology to allow operators to place raw or minimally prepared patient samples directly into our test cartridges and obtain clinically relevant results. We believe that our ePlex system offers certain advantages over competitive systems, including superior multiplexing capability, reduced hands-on processing time, testing capacity and flexibility, and other attributes. However, the commercial success of ePlex will depend on a number of factors, including, but not limited to:

- Our ability to consistently manufacture highly complex products that deliver valid and accurate results at the level required for large-scale market adoption;
- product reliability;
- overall market acceptance;
- our ability to offer a broad and clinically relevant test menu at a competitive price;
- our ability to effectively sell our products into integrated delivery networks and group purchasing organizations;
- adequate reimbursement for our products; and
- the development of clinical utility and health economic evidence to support adoption of our products

If we are unsuccessful in effectively commercializing our ePlex system at the levels we project within our expected time frame, or at all, our investment in anticipation of growth that does not materialize, or which develops more slowly than we expect, may harm our financial results, reduce our cash balances, and result in overcapacity, which may adversely affect our business and future prospects.

Our financial results will depend on the acceptance and increased demand among our target customers and the medical community of our molecular diagnostic technologies and products.

Our future success depends on the belief by our target customers and the medical community that our molecular diagnostic products, including our ePlex instrument and its test menu, are a reliable, medically-relevant, accurate and cost-effective replacement for other diagnostic testing methods. Our business success depends on our ability to convince our target customers to perform these tests internally with our products if they have historically outsourced their testing needs or have historically used non-molecular methods to perform such testing, or to replace their current molecular testing platforms with our system and its related test offerings.

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

- the relative convenience, ease of use, accuracy, reliability, validity, scalability, cost, and time-to-result of our diagnostic products over competing products;

- the introduction of new technologies and competing products that may make our technologies and products a less attractive solution for our target customers;
- the breadth and relevance of our menu of available diagnostic tests relative to our competitors;
- our success in training our customers in the proper use of our products;
- the acceptance in the medical community and key opinion leaders of our molecular diagnostic technology and products;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

Professional societies, government agencies, practice management groups, private health/science foundations and organizations involved in healthcare issues may publish guidelines, recommendations or studies for the healthcare and patient communities. Recommendations of government agencies or these other organizations may relate to such matters as cost-effectiveness and use of related products. Organizations like these have in the past made recommendations about our competitors' products, such as the need for less frequent screening tests, which could result in reduced product sales. Moreover, the perception by the investment community or stockholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect the prevailing market price for our common stock.

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

The markets for our technologies and products are highly competitive and we expect the intensity of competition to increase. We compete with companies engaged in the development, commercialization and distribution of similar products intended for clinical molecular diagnostic applications. Categories of our competitors include:

- companies developing and marketing multiplex molecular diagnostics systems, including: Luminex (which acquired Nanosphere, Inc.); bioMerieux (which acquired BioFire Diagnostics, Inc.); Abbott Molecular Diagnostics; Qiagen (which acquired Stat-Dx); Siemens (which acquired Fast Track Diagnostics); T2 BioSystems; Accelerate Diagnostics; Hologic, Inc.; Seegene; and Danaher Corporation (which acquired Cepheid);
- large hospital-based laboratories and reference laboratories who provide large-scale testing using their own proprietary testing methods, including Quest Diagnostics Incorporated and Laboratory Corporation of America; and
- companies that manufacture laboratory-based tests and analyzers, including: Danaher; Siemens; Hologic, Inc.; Qiagen NV; bioMérieux; Roche Diagnostics; and Abbott Molecular Diagnostics.

Our diagnostic tests also face competition from laboratory developed tests, or LDTs, developed by national and regional reference laboratories and hospitals. LDTs may not currently be subject to the same regulatory requirements, including those requiring clinical studies and FDA review and clearance or approval that may apply to our diagnostic products.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies, our competitors improve their current products and expand their menu of diagnostic tests, and as we expand our operations internationally. Many of our current and potential competitors have greater name recognition, more substantial intellectual property portfolios, longer operating histories, additional test menu, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, and more extensive manufacturing and distribution capabilities. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce enhanced and competitive technology to meet our customers' and prospective customers' needs on a timely basis.

In addition, we have limited marketing, sales and distribution experience and capabilities. Our ability to achieve profitability depends on attracting customers for our products and building brand loyalty. To successfully perform sales, marketing, distribution and customer support functions ourselves, we face a number of risks, including:

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

Some hospital-based and reference laboratories may not consider adopting our instrument systems unless we offer a broader menu of diagnostic tests or may choose not to convert from competitive products. In addition, in order to commercialize our products, we are required to undertake time consuming and costly development activities, including clinical studies for which the outcome is uncertain. Products that appear promising during early development and preclinical studies may, nonetheless, fail to demonstrate the results needed to support regulatory approval or, if approved, may not generate the demand we expect. If we are unable to effectively compete, our revenues and our ability to achieve profitability will be significantly impaired.

We may not expand sales of our ePlex system outside the United States at the levels we anticipate or within the time frame we anticipate.*

In June 2016, we obtained CE Mark under the European In-Vitro Diagnostic Devices Directive (98/79/EC) for our ePlex instrument and ePlex RP Panel; in April 2017, we obtained CE Mark for our ePlex BCID-FP Panel; and in June 2017, we obtained CE Mark for our ePlex BCID-GP Panel and BCID-GN Panel. We are commercializing our ePlex system in Europe utilizing a direct sales and technical support team in certain European countries. We have also engaged a number of distributors in certain international jurisdictions and we intend to further expand internationally over time. If we are unable to establish the infrastructure or recruit highly qualified personnel to support our international sales and support organization, if we fail to identify new distribution partners, or if we are unsuccessful in developing awareness and acceptance of our products and technology internationally, our anticipated revenue growth internationally may not materialize at the levels or within the time frame we expect, our customers may not receive the level of service or product dependability they expect from us, and our future financial performance may be adversely affected. Furthermore, the distributors we establish in particular geographic regions may not commit the necessary resources to market and sell our products to meet our expectations. If our distributors do not perform adequately or in compliance with applicable laws and regulations in particular geographic areas, or if we are unable to locate distributors in particular geographic areas, our ability to realize revenue growth based on sales outside the United States would be harmed.

If our customers are not adequately reimbursed or compensated for the use of our products, we may have difficulty selling our products.*

Our ability to sell our products depends in part on the extent to which reimbursement related to performing tests using our products is available from governmental authorities, such as Medicare and other domestic and foreign governmental programs, private insurance plans, managed care organizations and other organizations. There are ongoing efforts by governmental and third-party payors to contain or reduce the costs of healthcare coverage. For example, a number of Medicare Administrative Contractors (MACs) recently issued a final local coverage determination eliminating Medicare coverage for the use of certain multiplex molecular respiratory tests such as our ePlex RP Panel and XT-8 Respiratory Viral Panel (RVP) in an outpatient setting. As a result, this determination may negatively impact the use of our and certain of our competitors' multiplex respiratory tests within the geographic region covered by these MACs. In addition, if other MACs and private payors take a similar approach, this potential negative impact could affect the available market for our ePlex RP Panel and XT-8 RVP Panel in additional geographic regions and patient populations.

In addition, efforts to reform the healthcare delivery system in the United States and Europe has increased pressure on healthcare providers to reduce costs. For example, implementation of certain provisions of the Protecting Access to Medicare Act (PAMA) in the United States as of January 1, 2018 will have a negative impact on reimbursement payments from the Centers for Medicare and Medicaid Services (CMS) for our diagnostics tests paid under the Clinical Laboratory Fee Schedule (CLFS). Under these provisions of PAMA, payments under the CLFS are likely to be reduced annually for the next several years. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, either directly or indirectly, they may forego or reduce their purchase and use of our products or the price we may be able to charge for our products could be reduced.

Obtaining coverage and reimbursement approval for a product from each government or third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each government or third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs. Further, third-party payors may choose to reimburse our customers per test based on individual biomarker detection, rather than on the basis of the number of results given by the test. This may result in our customers electing to use separate tests to screen for each disease or condition so that they can receive reimbursement for each test they conduct. In that event, these entities may purchase separate tests for each disease, rather than products, such as ours, that can be used to return highly multiplexed test results.

From time to time we and our key suppliers experience, and may in the future experience difficulties scaling manufacturing operations to the levels required to support our anticipated growth in a timely and cost effective manner.*

To date, we have produced our products in limited quantities relative to the quantities necessary to achieve our desired revenue growth. Developing the necessary manufacturing and quality procedures internally and in conjunction with our key suppliers for a significant number of our newly developed, highly complex products and product components is a challenging process. From time to time we and our suppliers experience, and may in the future experience, manufacturing variability and may not be able to consistently produce sufficient quantities of high quality products and product components at the levels necessary to achieve our revenue growth expectations or to support our product development timelines. If we or our key suppliers continue to encounter difficulties in producing sufficient yields of high quality products or product components, or scaling manufacturing operations as a result of, among other things, process and manufacturing transfer complexities, quality control and quality assurance issues, and/or availability of subcomponents, equipment and raw material supplies, our reputation may be harmed and we may not achieve our anticipated financial results or product development goals within the time frame we expect, or at all.

Finding solutions to product quality, reliability, and variability issues are time consuming and expensive, and we may incur significant additional costs or lose revenue as a result of, among other things, delayed product introduction, product recalls, shipment holds, scrapped material, and warranty and service obligations.

In addition, we are implementing a number of measures to reduce the cost of manufacturing our ePlex products. If these efforts are unsuccessful, or if these efforts prove less successful than we anticipate or do not deliver the results within the timeframes we expect, we may not achieve our profitability targets in a timely manner, or at all.

To manage our anticipated future growth effectively, we must enhance our manufacturing and supply chain capabilities, infrastructure and operations, information technology infrastructure, and financial and accounting systems and controls. Organizational growth and scale-up of operations could strain our existing managerial, operational, financial and other resources. If our management is unable to effectively prepare for our expected future growth, our expenses may increase more than anticipated, our revenue could grow more slowly than expected, and we may not be able to achieve our commercialization, profitability, or product development goals. Our failure to effectively implement the necessary processes and procedures and otherwise prepare for our anticipated growth could have a material adverse effect on our future financial condition and prospects.

Disruptions in the supply of raw materials, consumable goods or other key product components, or issues associated with their cost or quality from our single source suppliers, could result in delays or difficulties successfully commercializing our ePlex system or a significant disruption in sales and profitability.

We must manufacture or engage third parties to manufacture components of our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. Our instrument systems and certain critical components are custom-made by only a few outside suppliers. In certain instances, we and our customers have a sole source supply for certain key products, product components and ancillary items used to run our tests. If we are unable to satisfy our forecasted demand from existing suppliers for our products, or we or our customers are unable to find alternative suppliers for key product components or ancillary items at reasonably comparable prices, it could have a material adverse effect on our financial condition and results of operations. Additionally, although we have entered into supply agreements with most of our suppliers of strategic reagents and parts to help ensure component availability and flexible purchasing terms with respect to the purchase of such components, if our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable, cost-effective alternative on reasonable terms, or at all, which could limit our ability to manufacture our products.

In determining the required quantities of our products and the manufacturing schedule, we must make significant judgments and estimates based on seasonality, inventory levels, current market trends, product development timelines, overall capacity, and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our products, there could be significant differences between our estimates and the actual amounts of products we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write-offs if we order more than we need.

Reliance on third-party manufacturers entails risk to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers;
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us;
- the potential obsolescence and/or inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;

- the inability to qualify alternate sources without impacting performance claims of our products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers;
- the potential for financial hardship or other detrimental circumstances at key suppliers that may impact our ability to source key materials or services required for the manufacturing of our products; and
- increases in prices of raw materials and key components.

The manufacturing operations for our test cartridges use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly and time consuming to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facilities or the facilities of any of our key suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, or otherwise, would limit our ability to meet customer demand for our products and would have a material adverse effect on our business, financial condition and results of operations. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

If our products do not perform as expected our operating results and business would suffer.

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

We currently manufacture our proprietary test cartridges at our Carlsbad, California manufacturing facilities. We outsource the manufacture of our ePlex instrument to Plexus. We currently maintain an inventory of XT-8 instruments and related components to satisfy the expected demand for our XT-8 system for the foreseeable future, as well as to service XT-8 instruments installed at customer locations. Plexus specializes in the manufacturing of electronic and electro-mechanical devices. While we work closely with Plexus to ensure continuity of supply while maintaining high quality and reliability, and we believe our current stock of XT-8 instruments and related components will be sufficient for our and our customers' anticipated needs, we cannot guarantee that these efforts will be successful.

If we experience a material defect or error in any of our current or future products, it could result in the loss or delay of revenues, increased costs, delayed or reduced market acceptance, damaged reputation, diversion of development and management resources, legal and/or regulatory claims, recalls, increased insurance costs or increased service and warranty costs, any of which could materially harm our business, financial condition and results of operations.

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

We may need to raise additional funds in the future, and such funds may not be available on a timely basis, or at all.

Until such time, if ever, as we can generate positive cash flows from operations, we will be required to finance our operations with our cash resources and amounts made available under our credit facility. We may need to raise additional funds in the future to support our operations. We cannot be certain that additional capital will be available as needed, on acceptable terms, or at all. If we require additional capital at a time when investment in our company, in molecular diagnostics companies, or the marketplace in general is limited, we may not be able to raise such funds at the time that we desire, or at all. If we do raise additional funds through the issuance of equity or convertible securities, the percentage ownership of holders of our common stock could be significantly diluted. In addition, newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds through collaborations and licensing arrangements, we could be required to relinquish significant rights to our technologies and products, or grant licenses on terms that are not favorable to us.

Our quarterly revenue and operating results may vary significantly and we may experience constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand.

Revenue from our infectious disease products fluctuates based upon the occurrence of related outbreaks and changes in testing recommendations and available therapies. Influenza and other respiratory-related outbreaks are usually more concentrated in the first and fourth quarters of the year. New information or the introduction of advanced treatment options with respect to a particular disease may also affect the rate of related diagnostic testing. Although certain infectious disease outbreaks tend to occur each year, the timing, severity and length of these incidents varies from one year to another and can vary across different patient populations. In addition, we may not accurately predict the impact of new therapies on disease prevalence or changes to infectious disease testing recommendations affecting our products. As a result of one or more of these factors, we may not be able to accurately forecast sales from our infectious disease products.

Also, unanticipated changes in customer demand for our products may result in constraints or inefficiencies related to our manufacturing, sales force, customer service and administrative infrastructure. These constraints or inefficiencies may adversely affect us as a result of delays, lost potential product sales or loss of current or potential customers due to their dissatisfaction.

Our revenue, results of operations and cash flows would suffer upon the loss of a significant customer.

Our largest customer, Laboratory Corporation of America, Inc., accounted for approximately 17% of our total revenue for the fiscal year ended December 31, 2017. The loss of a significant customer or a significant reduction in the amount of product ordered by our significant customers may adversely affect our revenue, results of operations and cash flows.

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

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which may be outside of our control. These factors include, but are not limited to:

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

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products, as well as our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with our ePlex system. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our business and financial condition.

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

We are investing significantly in the development of new ePlex molecular diagnostic tests to expand our future product offerings. Our newly developed ePlex tests will require 510(k) clearance or pre-market approval by the FDA prior to marketing those tests for commercial use in the United States. We submitted our BCID-GP Panel to the FDA for 510(k) clearance in June 2018. We also submitted our ePlex BCID-GN Panel and our ePlex BCID-FP Panel to the FDA for 510(k) clearance in September 2018. There are a number of potential risks associated with conducting clinical studies and obtaining regulatory clearance. For example, we may have difficulty maintaining the level of reliability and clinical accuracy required to complete clinical studies and obtain FDA clearance or approval. In addition, the FDA may require that we conduct additional studies that could impact the cost associated with product clearance and could potentially delay commercial launch of newly developed tests in the United States. We may be unsuccessful in obtaining FDA clearance for our expanding ePlex test menu within our expected time frame, or at all, which could adversely impact our future financial performance and cause our stock price to decline.

The regulatory environment is constantly evolving. For example, the FDA conducted a review of the pre-market clearance process in response to internal and external concerns regarding the 510(k) program and, in January 2011, announced 25 action items designed to make the process more rigorous and transparent. Some of these proposals, if enacted, could impose additional regulatory requirements for device manufacturers which could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. Similarly, the European Union, or EU, is transitioning from the existing European Directive 98/79/EC on in vitro diagnostic medical devices, or IVD Directive (IVDD), to the In Vitro Diagnostic Device Regulation, or IVDR. Under the IVDR, the classification of our molecular diagnostic products are impacted, and will result in additional regulatory requirements, which could delay our ability to CE Mark our products. Delays in receipt of, or failure to obtain, clearances or approvals for future products would result in delayed, or no, realization of revenues from such products and in substantial additional costs, which could decrease our profitability.

We must also comply with the applicable FDA and foreign regulatory agency post-market requirements, including Notified Body conformity assessments according to the IVDD. Any failure to maintain post-market compliance with FDA or foreign regulatory requirements could harm our business, operations, and/or financial condition.

We derive revenues from the sale of research use only, or RUO, tests and custom manufactured reagents, which are not intended for diagnostic purposes. Clinical laboratories are regulated under CLIA and may validate the clinical diagnostic use of an LDT specifically for use in their laboratory using any labeled products. The FDA has traditionally practiced enforcement discretion regarding the use of the LDTs for clinical diagnostic purposes. However, the FDA has promulgated draft guidance which outlines stringent regulatory requirements for CLIA labs in order to use LDTs for clinical diagnostic application. These proposed requirements, if implemented, may result in a significant reduction in the sale of our RUO or custom manufactured products, which could reduce our revenues and adversely affect our operations and/or financial condition.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

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

The False Claims Act, or the FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. We have implemented procedures designed to ensure our compliance with relevant legal requirements. Nevertheless, if our marketing, sales or other arrangements, including our reagent rental arrangements, were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition and results of operations.

The Health Care Act also imposes reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. In February 2013, the Centers for Medicare and Medicaid Services, or, CMS, released the final rule implementing the federal Physician Payments Sunshine Act, or the Sunshine Act. The law requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they furnish to physicians and teaching hospitals. These reporting requirements took effect on August 1, 2013. Failure to submit required information may result in significant civil monetary penalties. We expect compliance with the Sunshine Act to impose significant administrative and financial burdens on us.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

Legislative or regulatory healthcare reforms may have a material adverse effect on our business and results of operations.

Federal and state governments in the United States are undertaking efforts to control growing health care costs through legislation, regulation and voluntary agreements with medical care providers and third-party payors. In March 2010, Congress enacted the Patient Protection and Affordable Care Act, or the PPACA. While the PPACA involves expanding coverage to more individuals, it includes regulatory mandates and other measures designed to constrain medical costs. Among other requirements, the PPACA imposes a 2.3% excise tax on sales of medical devices by manufacturers. In December 2015, the excise tax was suspended for 2016 and 2017, and, in January 2018, the excise tax was further suspended until 2020. Taxable devices include certain medical devices intended for use by humans, with limited exclusions for devices purchased by the general public at retail for individual use. There is no exemption for small companies, and we paid the tax from 2013 through 2015. Recently, Congress and the new administration have proposed and taken various steps to revise, repeal, or delay implementation of various aspects of PPACA. If the PPACA is significantly revised, repealed, or if implementation of various aspects are delayed, such modification, repeal, or delay may impact our business, financial condition, results of operations, cash flows and the trading price of our securities. Complying with PPACA may significantly increase our tax liabilities and costs, which could adversely affect our business and financial condition.

The Budget Control Act of 2011 provided, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which began in 2013 and will remain in effect through 2025 unless additional Congressional action is taken. In addition to the potential impacts to PPACA under the current administration, there could be sweeping changes to the Budget Control Act and other healthcare reforms. For example, the Tax Cuts and Jobs Act enacted in December 2017 eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019. Additional changes to the PPACA remain possible. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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

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

The patent positions of medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States or in many foreign jurisdictions. Both the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, three Supreme Court cases, Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al., Mayo Collaborative Services v. Prometheus Laboratories, and Alice v. CLS Bank, have introduced additional questions regarding the patentability of isolated naturally occurring genes and gene fragments, proteins, peptides, natural products, and related diagnostic and therapeutic methods, which are likely to be resolved only through continued litigation. The overall impact of these decisions and others on the molecular diagnostics industry remains uncertain and our interpretation of the scope of these rulings on existing or future patents may be inaccurate.

There is a significant amount of uncertainty regarding the extent of patent protection and infringement. Companies may have filed pending patent applications that cover technologies we incorporate in our products. As a result, we could be subjected to substantial damages for past infringement or be required to modify our products or stop selling them if it is ultimately determined that our products infringe a third party's proprietary rights. Even if we are successful in defending against potential intellectual property infringement claims, we could incur substantial costs in doing so. Any litigation related to such claims could consume our resources and lead to significant damages, royalty payments, or an injunction on the sale of certain products. Any additional licenses to patented technology could obligate us to pay substantial additional royalties, which could adversely impact our product costs and harm our business.

If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.*

Our commercial success is dependent in part on obtaining, maintaining and enforcing intellectual property rights, including our patents and other intellectual property rights. If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products that are substantially the same as ours without incurring the sizable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that compete with our products. Currently, our patent portfolio is comprised on a worldwide basis of more than 100 owned and exclusively licensed patents and approximately 50 additional pending patent applications. In general, patents have a term of at least 20 years from the application filing date or earlier claimed priority date. Several of our pending applications have the potential to mature into patents that may expire between 2028 and 2038. However, not all of the pending or future patent applications owned by or licensed to us are guaranteed to mature into patents, and, moreover, issued patents owned by or licensed to us now or in the future may be found by a court to be invalid or otherwise unenforceable. Also, even if our patents are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor provide us with freedom to operate unimpeded by the patent rights of others.

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

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

Our manufacturing processes and facilities and those of some of our contract manufacturers must comply with the Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our devices. The FDA enforces the QSR through periodic announced and/or unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies.

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

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

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our products;
- total or partial suspension of production or distribution;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;

- refusal to permit the import or export of our products; and
- criminal prosecution.

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

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

The use of our diagnostic products by our customers is also affected by CLIA and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance, quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories from using some or all of our diagnostic products.

Our credit facility contains restrictions that limit our flexibility in operating our business.

We must comply with certain affirmative and negative covenants under our credit facility, including covenants that limit or restrict our ability to, among other things:

- incur additional indebtedness or issue certain preferred shares;
- pay dividends on, repurchase or make distributions in respect of, our capital stock or make other restricted payments;
- make certain investments or acquisitions;
- sell certain assets;
- create liens; or
- enter into certain transactions with our affiliates.

If we default under the agreement, because of a covenant breach or otherwise, the outstanding amounts thereunder could become immediately due and payable and the lenders could terminate all commitments to extend further financing.

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

We have a history of significant net losses and a limited history commercializing our molecular diagnostic products. Our net losses were approximately $38.9 million and $47.3 million million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $455.3 million. We expect to continue to incur significant expenses for the foreseeable future in connection with our ongoing operations, primarily related to expanding our commercial organization (sales and marketing) and manufacturing activities related to our ePlex system, maintaining our existing intellectual property portfolio, obtaining additional intellectual property rights, and investing in corporate infrastructure. We cannot provide any assurance that we will achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our limited commercialization history and the rapidly evolving nature of our target market, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, and failure to comply with these laws could harm our business and the price of our common stock.

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

Economic conditions and an uncertain economic outlook may adversely impact our business, results of operations, financial condition or liquidity.

Global economic conditions may remain challenging and uncertain for the foreseeable future. These conditions may not only limit our access to capital but also make it extremely difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U.S. and foreign businesses and consumers to slow spending on our products and services, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government's allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers, increase our allowance for doubtful accounts, and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we may not continue to experience the same loss rates that we have in the past. Additionally, these economic conditions and market turbulence may also impact our suppliers, causing them to be unable to supply sufficient quantities of customized components in a timely manner, thereby impairing our ability to manufacture on schedule and at commercially reasonable costs.

We are exposed to risks associated with long-lived and intangible assets that may become impaired and result in an impairment charge.

The carrying amounts of long-lived and intangible assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. These events or changes might include an inability to successfully deliver an instrument to the marketplace and attain customer acceptance, a change in the rights or use of licensed intellectual property, adjustments to our depreciation assumptions, or other matters. Adverse events or changes in circumstances may affect the estimated discounted future cash flows expected to be derived from long-lived and intangible assets. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. In the past we have incurred, and in the future we may incur, impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Providing instrument systems to our customers through reagent rental agreements may harm our liquidity.

Many of our systems are provided to customers via "reagent rental" agreements, under which customers are generally afforded the right to use the instrument in return for a commitment to purchase minimum quantities of reagents and test cartridges over a period of time. Accordingly, we must either incur the expense of manufacturing instruments well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our instrument. The amount of capital required to provide instrument systems to customers depends on the number of systems placed. Our ability to generate capital to cover these costs depends on the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we cannot sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected.

We use hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

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

If we are unable to retain key employees or hire additional skilled employees, we may be unable to achieve our goals.

Our performance is substantially dependent on the performance of our senior management. Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. Our senior managers can terminate their relationship with us at any time. The loss of services of any of these key personnel could significantly reduce our operational effectiveness and investor confidence and our stock price could decline. We do not maintain key-man life insurance on any of our employees.

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

Cyberattacks and other security breaches could compromise our proprietary information which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is critical to our operations, business strategy, and reputation. Computer hackers may attempt to penetrate our computer systems or our third party IT service providers' systems and, if successful, misappropriate our proprietary information. In addition, an employee, contractor, or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we will continue to implement additional protective measures to reduce the risk of and detect cyberattacks, these incidents are becoming more sophisticated and frequent, and the techniques used in such attacks evolve rapidly and are difficult to detect. Despite our cybersecurity measures, our information technology networks and infrastructure may still be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our, or our third party IT service providers' data security and access to, or public disclosure or loss of, confidential business or proprietary intellectual property information could disrupt our operations, damage our reputation, provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

Information technology systems implementation issues could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we have implemented an enterprise resource planning software system. To more fully realize the potential of this system, we are continually reassessing and upgrading processes and this may be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the operation of this system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flows and to otherwise operate our business in a secure environment, all of which could adversely affect our financial results, stock price and reputation.

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

The Company has generated federal and state net operating loss, or NOL, carryforwards from the recurring net losses it has reported since inception. The federal NOL carryforwards will expire in varying amounts through 2036. Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, generally imposes an annual limitation on the amount of federal and state NOL carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in stock ownership. We have determined that we have experienced multiple ownership changes under Section 382 of the Code. Our ability to use the current federal and state NOL carryforwards may also be limited by the issuance of common stock in the future. To the extent our use of federal and state NOL carryforwards is limited, our income may be subject to corporate income tax earlier than it would if we were able to use the state or federal NOL carryforwards. We have recorded a full valuation allowance against our federal and state net deferred tax assets.

Provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- provide that our stockholders may remove our directors only for cause;
- establish a classified board of directors, such that not all members of the Board of Directors may be elected at one time;
- authorize our Board of Directors to issue without stockholder approval up to 100,000,000 shares of common stock, that, if issued, would dilute our stock ownership and could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- authorize our Board of Directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting or by unanimous written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 80% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

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

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	Fourth Amendment to Lease dated July 25, 2018 by and among Brookwood CB I, LLC and Brookwood CB II, LLC, and the Company (incorporated by reference to our 10-Q filed with the SEC on July 30, 2018).
10.2	Sixth Amendment to the Loan and Security Agreement dated as of September 28, 2018 by and among GenMark Diagnostics, Inc., as borrower, its domestic subsidiaries, as guarantors, Solar Senior Capital Ltd., as administrative and collateral agent, and certain other financial institutions.+
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.

+ GenMark has requested confidential treatment with respect to certain portions of this exhibit.

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:	October 29, 2018	By:	/s/ HANY MASSARANY
			Hany Massarany
			President and Chief Executive Officer
			(Principal Executive Officer)
Date:	October 29, 2018	By:	/s/ SCOTT MENDEL
			Scott Mendel
			Chief Financial Officer
			(Principal Financial and Accounting Officer)

*Portions of this Exhibit have been redacted pursuant to a request for confidential treatment under Rule 24b-2 of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended. Such redacted portions have been replaced with "***" in this Exhibit. An unredacted version of this document has been filed separately with the Securities and Exchange Commission along with the request for confidential treatment*

Execution Version

SIXTH AMENDMENT TO LOAN AND SECURITY AGREEMENT
AND
FIFTH AMENDMENT TO AMENDED AND RESTATED FEE LETTER

THIS **SIXTH AMENDMENT TO LOAN AND SECURITY AGREEMENT AND FIFTH AMENDMENT TO AMENDED AND RESTATED FEE LETTER** (this "**Amendment**"), dated as of September 28, 2018 (the "**Sixth Amendment Effective Date**"), is made among GenMark Diagnostics, Inc., a Delaware corporation (the "**Borrower**"), the other Loan Parties party to that certain Loan and Security Agreement (as defined below), Solar Senior Capital Ltd., in its capacity as administrative and collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Agent**"), SUNS SPV LLC, as lender, North Mill Capital LLC, as lender, Crystal Financial LLC, as lender, SCP Private Credit Income Fund SPV LLC, as lender, SCP Private Credit Income Fund LP, as lender, and the other Lenders party to the Loan and Security Agreement or otherwise a party thereto from time to time (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the other Loan Parties, the Lenders and Agent are parties to a Loan and Security Agreement dated as of January 12, 2015 (as amended by that certain letter agreement dated as of September 30, 2015, that certain letter agreement dated as of March 17, 2016, that certain First Amendment to Loan and Security Agreement dated as of July 27, 2016, that certain Second Amendment to Loan and Security Agreement dated as of February 27, 2017, that certain Third Amendment to Loan and Security Agreement and Second Amendment to Fee Letter dated as of May 31, 2017 (the "**Third Amendment**"), that certain Fourth Amendment to Loan and Security Agreement and Third Amendment to Fee Letter, dated as of June 7, 2017 (the "**Fourth Amendment**"), that certain Fifth Amendment to Loan and Security Agreement and Fourth Amendment to Fee Letter, dated as of December 13, 2017 (the "**Fifth Amendment**"), and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "**Loan and Security Agreement**"). The Borrower and Agent are parties to that certain Amended and Restated Fee Letter dated January 9, 2015 (as amended pursuant to that certain First Amendment to Amended and Restated Fee Letter dated as of February 27, 2017, the Third Amendment, the Fourth Amendment, the Fifth Amendment, and as further amended, amended and restated, supplemented or otherwise modified from time to time, the "**Fee Letter**"). The Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement and the Fee Letter. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the preamble and recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement and Fee Letter.

(i) Effective as of the Sixth Amendment Effective Date, the Loan and Security Agreement shall be amended as follows:

(i) *Section 2.1(a)*. Section 2.1(a)(iii-v) shall be amended and restated as follows, with a new Section 2.1(a)(vi) added as follows:

"(iii) Subject to the terms and conditions of this Agreement and in reliance upon the representations and warranties of the Loan Parties contained herein, each Lender with a Term Loan C Commitment severally and not jointly agrees to make a loan (the "Term Loan C") in Dollars to Borrower on any Business Day during the period from the First Amendment Effective Date to and including the Term Loan C Commitment Termination Date, in an amount equal to such Lender's Term Loan C Commitment. Upon the funding of such Term Loan C, the Term Loan C Commitment shall terminate.

(iv) Subject to the terms and conditions of this Agreement and in reliance upon the representations and warranties of the Loan Parties contained herein, each Lender with a Term Loan D Commitment severally and not jointly agrees to make a loan (the "Term Loan D", and together with the Term Loan A, Term Loan B, and Term Loan C, each a "Term Loan" and collectively, the "Term Loans") in Dollars to Borrower on the Sixth Amendment Effective Date, in an amount equal to such Lender's Term Loan D Commitment.

(v) Once a Term Loan is repaid or prepaid, it cannot be reborrowed.

(vi) Each Term Loan made by each Lender is evidenced by this Agreement, and if requested by such Lender, a Note payable to such Lender."

(ii) *Sections 2.1(b)(i), 2.2(a)(ii), 2.2(b), 2.4(a), 2.4(b), 2.4(e), 2.4(f), 2.4(g)(y), 2.5(a)(ii), 2.5(d), 2.6(c), and 9.10(a)(ii)*. Sections 2.1(b)(i), 2.2(a)(ii), 2.2(b) (with respect to the Revolving Loans only), 2.4(a) (with respect to the Revolving Loans only), 2.4(b) (with respect to the Revolving Loans only), 2.4(e) (with respect to the Revolving Loans only), 2.4(f) (with respect to the Revolving Loans only), 2.4(g)(y), 2.5(a)(ii), 2.5(d), 2.6(c) and 9.10(a)(ii) are each hereby amended by replacing (or as indicated above with respect to the Revolving Loans only, by replacing only in connection with the application of such provision to the Revolving Loans) the word "EWB" with the word "Agent" in each instance therein.

(iii) *Section 2.4(b)(i)*. Section 2.4(b)(i) shall be amended and restated as follows:

"(i) Term Loans. Commencing on the Initial Term Loan Payment Date, and continuing on each Scheduled Payment Date thereafter, Borrower shall make consecutive equal monthly payments of principal, in arrears, to each Lender in accordance with their Pro Rata Shares, as calculated by Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan and (2) the Term Loan Principal Payment Schedule. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Final Maturity Date."

(iv) *Section 2.6(b)*. Section 2.6(b) shall be amended and restated as follows:

"(b) Final Payment Fee. On the Final Maturity Date or, if earlier, the date upon which the aggregate outstanding principal amount of the Term Loans is required to be repaid in full (whether by scheduled payment, voluntary prepayment, mandatory prepayment pursuant to Section 2.5(b)(i), acceleration of the Obligations pursuant to Section 8.2 or otherwise), Borrower shall pay to each Lender a non-refundable fee as set forth below (the "Final Payment Fee"):

Lender	Final Payment Fee
SUNS SPV LLC	$***
North Mill Capital LLC	$***
Crystal Financial LLC	$***
SCP Private Credit Income Fund SPV LLC	$***
Aggregate Final Payment Fee	$***

The Final Payment Fee shall be deemed to be fully earned on the Closing Date. If for any reason any Term Loan is prepaid in part prior to the Final Maturity Date, (i) Borrower shall pay on the date of any such partial prepayment a fee equal to a proportional part of the Final Payment Fee, and (ii) the Final Payment Fee due and payable on the Final Maturity Date or, if earlier, the date upon which the aggregate outstanding principal amount of the Term Loans is required to be repaid in full (whether by scheduled payment, voluntary prepayment, mandatory prepayment pursuant to Section 2.5(b)(i), acceleration of the Obligations pursuant to Section 8.2 or otherwise), shall be reduced by the aggregate amount of any such payments described in the foregoing clause (i)."

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

(v) *Section 11*. The following definitions are added to Section 11 in their proper alphabetical order:

"Sixth Amendment Effective Date" means September 28, 2018.

"Term Loan D Commitment" means, with respect to each Lender, the amount set forth opposite such Lender's name on Schedule A hereto under the caption "Term Loan D Commitment", as amended from time to time to reflect any permitted assignments and as such amount may be reduced or terminated pursuant to this Agreement. "Term Loan D Commitments" means the Term Loan D Commitments of all Lenders with a Term Loan D Commitment.

"Term Loan Principal Payment Schedule" means the payment schedule set forth in Schedule B attached hereto, as amended or updated by Agent from time to time in accordance with the terms of the Loan Documents.

(vi) *Section 11*. The following definitions shall be amended and restated as follows:

"Commitments" means the Term Loan Commitments and the Revolving Loan Commitments.

"Final Maturity Date" means January 1, 2021.

"Initial Term Loan Payment Date" means January 1, 2020.

"Note" means a promissory note of Borrower, in form and substance satisfactory to Agent, payable to a Lender in a principal amount equal to the amount of such Lender's applicable Term Loan Commitment or applicable Revolving Loan Commitment.

"Term Loan Commitment" or "Term Loan Commitments" means the Term Loan A Commitments, the Term Loan B Commitments, the Term Loan C Commitments, and the Term Loan D Commitments.

(vii) *Section 11*. Clauses (h), (i) and (j) of the definition of "Permitted Liens" shall be amended and restated as follows:

"(h) Liens arising by reason of zoning restrictions, easements, licenses, reservations, restrictions, covenants, rights-of-way, encroachments, minor defects or irregularities in title (including leasehold title) and other similar encumbrances on the use of real property that do not materially (1) impair the value or marketability of such real property or (2) interfere with the ordinary conduct of the business conducted and proposed to be conducted at such real property, and (i) licenses described in clause (c) of the definition of "Permitted Disposition" and (j) Liens in favor of Beach Business Bank on cash collateral securing Indebtedness permitted pursuant to clause (f) of the definition of "Permitted Indebtedness" so long as the amount of such cash collateral does not exceed the face value of the Landlord Letter of Credit."

(viii) *Section 11*. Clause (a) of the definition of "Pro Rata Share" shall be amended and restated as follows:

.

"(a) with respect to a Lender's obligation to make a Term Loan and right to receive payments of interest, fees and principal with respect thereto at any time, the percentage obtained by dividing (i) such Lender's applicable Term Loan Commitment at such time, as the case may be (or if the applicable Term Loan Commitment of such Lender is terminated at such time, the aggregate outstanding principal amount of the applicable Term Loans at such time owing to such Lender), by (ii) the applicable Term Loan Commitments of all Lenders at such time (or, if the applicable Term Loan Commitments of all such Lenders are terminated at such time, the aggregate outstanding principal amount of the applicable Term Loans owing to all Lenders at such time);"

(ix) *Section 11*. The defined terms "Applicable Final Payment Fee Percentage" and "EWB" shall be deleted.

(x) *Schedule A*. Schedule A of the Loan and Security Agreement, the Schedule of Lenders and Commitments, shall be amended and restated in its entirety with Schedule 1 attached hereto.

(xi) *Schedule B*. A new Schedule B to the Loan and Security Agreement, the Term Loan Principal Payment Schedule, attached as Schedule 2 hereto, shall be added to the Loan and Security Agreement.

(b) Effective as of the Sixth Amendment Effective Date, the Fee Letter shall be amended as follows:

(i) *Paragraph (b)*. Paragraph (b) shall be amended and restated as follows:

> "(b) Final Payment Fee. On the Final Maturity Date or, if earlier, the date upon which the aggregate outstanding principal amount of the Term Loans is required to be repaid in full (whether by scheduled payment, voluntary prepayment, mandatory prepayment, acceleration of the Obligations, or otherwise), Borrower shall pay a non-refundable fee of *** ($***). The Final Payment Fee shall be deemed to be fully earned on the Closing Date. If for any reason any Term Loan is prepaid in part prior to the Final Maturity Date, (i) Borrower shall pay on the date of any such partial prepayment a fee equal to a proportional part of the Final Payment Fee, and (ii) the Final Payment Fee due and payable on the Final Maturity Date or, if earlier, the date upon which the aggregate outstanding principal amount of the Term Loans is required to be repaid in full (whether by scheduled payment, voluntary prepayment, mandatory prepayment, acceleration of the Obligations, or otherwise), shall be reduced by the aggregate amount of any such payments described in the foregoing clause (i)."

(ii) *Paragraph (d)*. Paragraph (d) shall be amended and restated as follows:

> "(d) Annual Management Fee: A non-refundable annual management fee, for the account of Agent, in an amount equal to $*** per year, which fee shall be fully earned, due and payable in full in advance, on the Closing Date and on each anniversary thereof."

(c) **Revolving Credit Facility Fee**. On or before the Sixth Amendment Effective Date, Borrower shall pay a fee of *** ($***) to Agent, to be shared among the Lenders in accordance with their Pro Rata Shares of Revolving Loan Commitments, which fee shall be fully earned on the Sixth Amendment Effective Date. For the avoidance of doubt, such fee is part of the Obligations.

(d) **Amendment Fee**. On or before the Sixth Amendment Effective Date, Borrower shall pay an amendment fee of *** Dollars ($***) to Agent, to be shared among the Lenders in accordance with their Pro Rata Shares of Term Loan Commitments, which fee shall be fully earned on the Sixth Amendment Effective Date. For the avoidance of doubt, such amendment fee is part of the Obligations.

(e) **References Within Loan and Security Agreement and Fee Letter**. Each reference in the Loan and Security Agreement and the Fee Letter, as applicable, to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement or the Fee Letter, as applicable, as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Borrower shall have paid (i) the fees set forth in Sections 2(c) and 2(d), (ii) all invoiced costs and expenses then due in accordance with Section 5(d), (iii) all amounts due to East West Bank as set forth on Exhibit A attached hereto, and (iv) all other fees, costs and expenses, if any, due and payable as of the Sixth Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Agent shall have received this Amendment, executed by Agent, the Lenders and the Loan Parties.

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

(c) **Representations and Warranties; No Default**. On the Sixth Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement and Fee Letter contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Sixth Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Defaults or Events of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, each Loan Party hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Effect; and (c) that, other than as updated on Exhibit B hereto, the information included in the Perfection Certificate delivered to Agent on June 7, 2016, as updated by Exhibit B attached to the Third Amendment and Exhibit A attached to the Fifth Amendment, remains true and correct. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete as of such earlier date).

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement, the Fee Letter and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. Each Loan Party hereby reaffirms the grant of security under Section 3.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement and all Guaranteed Obligations (as defined in the Guaranty), as applicable, including without limitation any Term Loans funded on or after the Sixth Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Sixth Amendment Effective Date specifying its objection thereto.

(c) **No Reliance**. Each Loan Party hereby acknowledges and confirms to Agent and the Lenders that such Loan Party is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(d) **Costs and Expenses**. The Borrower agrees to pay to Agent within ten (10) days of its receipt of an invoice (or on the Sixth Amendment Effective Date to the extent invoiced on or prior to the Sixth Amendment Effective Date), the reasonable, documented, out-of-pocket costs and expenses of Agent and the Lenders party hereto, and the reasonable, documented, fees and disbursements of counsel to Agent and the Lenders party hereto, in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Sixth Amendment Effective Date or after such date.

(e) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(f) **Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.**

(g) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(h) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(i) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(j) **Loan Documents**. This Amendment and the documents related hereto shall constitute Loan Documents.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

GENMARK DIAGNOSTICS, INC.,
as Borrower

By: /s/ Scott Mendel
Title: Chief Financial Officer

GUARANTORS

CLINICAL MICRO SENSORS, INC.,
as Guarantor

By: /s/ Scott Mendel
Title: Chief Financial Officer

OSMETECH, INC.,
as Guarantor

By: /s/ Scott Mendel
Title: Chief Financial Officer

AGENT:

SOLAR SENIOR CAPITAL, LTD.,
as Agent

By: /s/ Richard L. Peteka
Name: /s/ Richard L. Peteka
Title: Chief Financial Officer

LENDERS:

SUNS SPV LLC,
as Lender

By: /s/ Richard L. Peteka
Name: /s/ Richard L. Peteka
Title: Chief Financial Officer

NORTH MILL CAPITAL, LLC,
as Lender

By: /s/ Stephen Carroll
Name: /s/ Stephen Carroll
Title: EVP & CFO

CRYSTAL FINANCIAL, LLC,
as Lender

By: /s/ Evren Ozargun
Name: /s/ Evren Ozargun
Title: Senior Managing Director

SCP PRIVATE CREDIT INCOME FUND SPV LLC,
as Lender

By: /s/ Richard L. Peteka
Name: /s/ Richard L. Peteka
Title: Chief Financial Officer

SCP PRIVATE CREDIT INCOME FUND LP,
as Lender

By: /s/ Richard L. Peteka
Name: /s/ Richard L. Peteka
Title: Chief Financial Officer

SCHEDULE 1

SCHEDULE A TO LOAN AND SECURITY AGREEMENT

COMMITMENTS AS OF THE SIXTH AMENDMENT EFFECTIVE DATE

Name of Lender	Term Loan A Commitments	Pro Rata Share of Term Loan A Commitments	Term Loan B Commitments	Pro Rata Share of Term Loan B Commitments	Term Loan C Commitments	Pro Rata Share of Term Loan C Commitments	Term Loan D Commitments	Pro Rata Share of Term Loan D Commitments	Revolving Loan Commitments	Pro Rata Share of Revolving Loan Commitment	Total Commitments	Pro Rata Share of Total Commitments
***	***	***	***	***	***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***	***	***	***	***	***
***	***	***	***	***	***	***	***	***	***	***	***	***
TOTAL	$7,619,047.60	100.0%	$7,619,047.60	100.0%	$12,000,000.00	100.0%	$663,455.12	100.0%	$5,000,000.00	100.0%	$32,901,550.32	100.0%

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

SCHEDULE B TO LOAN AND SECURITY AGREEMENT

TERM LOAN PRINCIPAL PAYMENT SCHEDULE

Scheduled Payment Date	Amount
January 1, 2020	$1,162,564.60
February 1, 2020	$1,162,564.60
March 1, 2020	$1,162,564.60
April 1, 2020	$1,162,564.60
May 1, 2020	$1,162,564.60
June 1, 2020	$1,162,564.60
July 1, 2020	$1,162,564.60
August 1, 2020	$1,162,564.60
September 1, 2020	$1,162,564.60
October 1, 2020	$1,162,564.60
November 1, 2020	$1,162,564.60
December 1, 2020	$1,162,564.60
January 1, 2021	$13,950,775.16
Total	$27,901,550.32

EXHIBIT A

AMOUNTS DUE TO EAST WEST BANK

Interest:	$***
Unused Revolving Commitment:	$***

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

EXHIBIT B

UPDATES TO PERFECTION CERTIFICATE

***

*** Portions of this page have been omitted pursuant to a request for Confidential Treatment filed separately with the Commission.

Exhibit 31.1

CERTIFICATIONS

I, Hany Massarany, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 of GenMark Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2018

By: /s/ Hany Massarany
Hany Massarany
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Scott Mendel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 of GenMark Diagnostics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: October 29, 2018

By: /s/ Scott Mendel

Scott Mendel

Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of GenMark Diagnostic, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), we, Hany Massarany, President and Chief Executive Officer of the Company, and Scott Mendel, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Periodic Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 29, 2018

By: /s/ Hany Massarany
Hany Massarany
President and Chief Executive Officer

Date: October 29, 2018

By: /s/ Scott Mendel
Scott Mendel
Chief Financial Officer