

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 29, 2018

GENMARK DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number: 001-34753

Delaware
(State or other jurisdiction
of incorporation)

27-2053069
(I.R.S. Employer
Identification No.)

5964 La Place Court
Carlsbad, California 92008
(Address of principal executive offices, including zip code)

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

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

Emerging Growth Company

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 Selection 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On October 29, 2018, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2018. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained under this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this Current Report:

99.1 Press release dated October 29, 2018

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 hereunto duly authorized.

GENMARK DIAGNOSTICS, INC.

Date: October 29, 2018

/s/ Scott Mendel

Scott Mendel

Chief Financial Officer

EXHIBITS

Exhibit Number	Description
99.1	Press release dated October 29, 2018

October 29, 2018

GenMark Diagnostics Reports Third Quarter 2018 Results

CARLSBAD, Calif - GenMark Diagnostics, Inc. (Nasdaq: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the third quarter ended September 30, 2018.

Highlights

- Recognized revenues of \$15.8 million, an increase of 36% over the prior year period
- Placed 45 net new ePlex analyzers, expanding the global installed base to 312 placements
- Submitted two additional ePlex Blood Culture Identification (BCID) Panels to the U.S. Food and Drug Administration (FDA): Gram-Negative (BCID-GN) Panel and Fungal Pathogen (BCID-FP) Panel

“Q3 was another quarter of solid performance across several important areas of our business. Our sales force delivered strong revenues and expanded our installed base of ePlex analyzers, while our operations team continued to enhance manufacturing and cost efficiencies,” said Hany Massarany, President and Chief Executive Officer. “We are especially pleased to have now completed all three submissions of our blood culture identification panels to the FDA. We are confident in the significant opportunity for these panels and currently preparing the market, as well as our organization, for a successful launch in the US.”

Third Quarter Financial Results

Revenue was \$15.8 million in the third quarter of 2018, an increase of 36% versus \$11.6 million in the third quarter of 2017. Gross profit was \$5.6 million, or 36% of revenue, compared with \$4.2 million, or 36% of revenue in the same period of 2017.

Operating expenses for the third quarter of 2018 were \$16.2 million compared to \$18.9 million in the same period of 2017. The decrease was largely due to reduced ePlex development expenses.

Loss per share was \$0.20 for the third quarter of 2018, compared to a \$0.28 loss per share in the third quarter of 2017.

The Company ended the quarter with \$42.7 million in cash and investments.

Guidance for Full Year 2018

GenMark is reconfirming 2018 revenue guidance of \$68 to \$72 million. Gross margin is now expected to be in the 28-30% range. The range of expected ePlex placements has been narrowed to 150-160 net new analyzers, and the annuity per ePlex placement remains the same in the \$100,000 to \$120,000 range.

Webcast and Conference Call Information

GenMark will be hosting a conference call to discuss third quarter results in further detail on Monday, October 29, 2018 starting at 4:30 p.m. ET. The conference call will be concurrently webcast. The link to the webcast will be available on the GenMark Diagnostics, Inc. website at www.genmarkdx.com under the investor relations section and will be archived for future reference. To listen to the conference call, please dial (877) 312-5847 (US/Canada) or (253) 237-1154 (International) and use the conference ID number 3389197 approximately five minutes prior to the start time.

About GenMark Diagnostics

GenMark Diagnostics (NASDAQ: GNMK) is a leading provider of multiplex molecular diagnostic solutions designed to enhance patient care, improve key quality metrics, and reduce the total cost-of-care. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's eSensor XT-8® and ePlex® systems are designed to support a broad range of molecular diagnostic tests with compact, easy-to-use workstations and self-contained, disposable test cartridges. GenMark's ePlex: *The True Sample-to-Answer Solution*™ is designed to optimize laboratory efficiency and address a broad range of infectious disease testing needs, including respiratory, bloodstream, and gastrointestinal infections. For more information, visit www.genmarkdx.com.

Safe Harbor Statement

This press release includes forward-looking statements regarding events, trends and business prospects, which may affect our future operating results and financial position. Such statements, including, but not limited to, those regarding our future financial performance, regulatory submissions and approvals, and the timely and effective commercialization and clinical impact of our ePlex system, are all subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, our ability to successfully commercialize our ePlex system and its related test menu in a timely manner, constraints or inefficiencies caused by unanticipated acceleration and deceleration of customer demand, our ability to successfully expand sales of our product offerings outside the United States, and third-party payor reimbursement to our customers, as well as other risks and uncertainties described under the “Risk Factors” in our public filings with the Securities and Exchange Commission. We assume no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made.

Investor Relations Contact

Lynn Pieper Lewis or Leigh Salvo

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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

GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		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)

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

	Nine Months Ended September 30,	
	2018	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

