

GENMARK DIAGNOSTICS, INC.

FORM 8-K (Current report filing)

Filed 08/01/17 for the Period Ending 08/01/17

Address	5964 LA PLACE COURT CARLSBAD, CA 92008
Telephone	(760) 448-4300
CIK	0001487371
Symbol	GNMK
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

**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): August 1, 2017

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 August 1, 2017, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2017. 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 August 1, 2017.

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: August 1, 2017

/s/ Scott Mendel

Scott Mendel

Chief Financial Officer

EXHIBITS

Exhibit Number	Description
99.1	Press release dated August 1, 2017.

August 1, 2017

GenMark Reports Second Quarter 2017 Results
Second Quarter Revenue of \$12.4 million
Ended the Quarter with Over 80 ePlex[®] Instruments Installed at Customer Sites

CARLSBAD, Calif.-(BUSINESS WIRE) - GenMark Diagnostics, Inc. (Nasdaq:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the second quarter ended June 30, 2017.

Revenue for the second quarter of 2017 was \$12.4 million, a decrease of 1% over the prior year period. Annuity per XT-8 analyzer was \$69 thousand in the second quarter and in the mid-\$70 thousand range over the last 4 quarters.

Gross profit for the second quarter was \$4.9 million, or 40% of revenue, compared with \$7.8 million, or 62% of revenue in the same period of 2016.

“We are delighted to have accomplished several important goals in the second quarter. Our team achieved FDA 510(k) clearance of the ePlex instrument and Respiratory Pathogen Panel as well as CE Mark for all three of our Blood Culture ID Panels,” said Hany Massarany, President and Chief Executive Officer of GenMark. “In addition, we significantly strengthened our balance sheet, which will enable us to bring even more focus to the global commercialization of our ePlex System and its menu expansion,” added Massarany.

Operating expenses for the second quarter of 2017 were \$22.2 million compared to \$20.4 million in the same period for 2016. The increase was mainly driven by Marketing and Sales expenses as the Company continues to expand its commercial organization in support of the global ePlex product launch.

Loss per share was \$0.37 per share for the second quarter of 2017, compared to a \$0.30 loss per share in the second quarter of 2016.

The Company ended the quarter with \$106.5 million in cash and cash equivalents.

The Company will be hosting a conference call to discuss second quarter results in further detail on Tuesday, August 1, 2017 starting at 8:30 a.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 48903152 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 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.

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	June 30, 2017	December 31, 2016
Current assets		
Cash and cash equivalents	\$ 88,427	\$ 15,959
Marketable securities	18,091	25,607
Accounts receivable, net of allowances of \$2,773 and \$2,740, respectively	7,268	9,048
Inventories	7,105	6,633
Prepaid expenses and other current assets	1,324	1,202
Total current assets	122,215	58,449
Property and equipment, net	19,778	18,268
Intangible assets, net	2,923	2,670
Restricted cash	758	758
Other long-term assets	179	179
Total assets	\$ 145,853	\$ 80,324
Current liabilities		
Accounts payable	\$ 6,665	\$ 8,703
Accrued compensation	4,502	5,650
Loan payable	19,275	7,935
Other current liabilities	3,557	4,133
Total current liabilities	33,999	26,421
Long-term liabilities		
Deferred rent	3,378	3,652
Long-term debt	14,901	11,880
Other non-current liabilities	222	220
Total liabilities	52,500	42,173
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 54,665 and 46,554 shares issued and outstanding as of June 30, 2017 and December 31, 2016, respectively	6	4
Additional paid-in capital	480,507	393,322
Accumulated deficit	(387,176)	(355,270)
Accumulated other comprehensive income	16	95
Total stockholders' equity	93,353	38,151
Total liabilities and stockholders' equity	\$ 145,853	\$ 80,324

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
Revenue				
Product revenue	\$ 12,291	\$ 12,425	\$ 24,761	\$ 23,384
License and other revenue	68	87	133	192
Total revenue	12,359	12,512	24,894	23,576
Cost of revenue	7,475	4,720	13,827	9,095
Gross profit	4,884	7,792	11,067	14,481
Operating expenses				
Sales and marketing	5,159	3,300	9,853	7,009
General and administrative	3,978	3,876	7,988	7,296
Research and development	13,014	13,204	24,049	25,472
Total operating expenses	22,151	20,380	41,890	39,777
Loss from operations	(17,267)	(12,588)	(30,823)	(25,296)
Other income (expense)				
Interest income	54	26	106	55
Interest expense	(755)	(308)	(1,261)	(585)
Other income	56	(42)	151	(9)
Total other expense	(645)	(324)	(1,004)	(539)
Loss before provision for income taxes	(17,912)	(12,912)	(31,827)	(25,835)
Income tax expense	77	(5)	78	31
Net loss	\$ (17,989)	\$ (12,907)	\$ (31,905)	\$ (25,866)
Net loss per share, basic and diluted	\$ (0.37)	\$ (0.30)	\$ (0.67)	\$ (0.60)
Weighted average number of shares outstanding, basic and diluted	48,067	42,864	47,460	42,768
Other comprehensive loss				
Net loss	\$ (17,989)	\$ (12,907)	\$ (31,905)	\$ (25,866)
Foreign currency translation adjustments	3	(34)	94	13
Net unrealized gains (losses) on marketable securities, net of tax	1	(5)	(15)	(21)
Comprehensive loss	\$ (17,985)	\$ (12,946)	\$ (31,826)	\$ (25,874)

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

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss	\$ (31,905)	\$ (25,866)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,454	1,791
Amortization of premiums on investments	30	35
Amortization of deferred debt issuance costs	493	169
Stock-based compensation	5,602	4,540
Provision for bad debt	32	23
Non-cash inventory adjustments	565	92
Other non-cash adjustments	(123)	19
Changes in operating assets and liabilities:		
Accounts receivable	1,795	1,406
Inventories	(2,563)	306
Prepaid expenses and other assets	(119)	(721)
Accounts payable	(3,134)	1,289
Accrued compensation	(1,170)	1,119
Other liabilities	(124)	303
Net cash used in operating activities	(28,167)	(15,495)
Investing activities		
Payments for intellectual property licenses	—	(800)
Purchases of property and equipment	(2,535)	(2,404)
Purchases of marketable securities	(10,496)	(2,532)
Proceeds from sales of marketable securities	13,896	—
Maturities of marketable securities	4,100	4,650
Net cash provided by (used in) investing activities	4,965	(1,086)
Financing activities		
Proceeds from issuance of common stock	86,835	449
Costs incurred in conjunction with stock issuance	(5,171)	—
Principal repayment of borrowings	(964)	(17)
Proceeds from borrowings	15,000	10,000
Costs associated with debt issuance	(187)	(30)
Proceeds from stock option exercises	170	352
Net cash provided by financing activities	95,683	10,754
Effect of exchange rate changes on cash	(13)	3
Net increase (decrease) in cash and cash equivalents	72,468	(5,824)
Cash and cash equivalents at beginning of period	15,959	35,385
Cash and cash equivalents at end of period	\$ 88,427	\$ 29,561
Non-cash investing and financing activities		
Transfer of instruments from (to) property and equipment into (from) inventory	\$ (1,534)	\$ 42
Property and equipment costs included in accounts payable	713	588
Intellectual property acquisitions included in other current liabilities	500	—
Supplemental cash flow disclosures		
Cash paid for income taxes, net	54	13
Cash received for interest	187	51
Cash paid for interest	574	408



GenMark Diagnostics, Inc.
Hany Massarany President/Chief Executive Officer
760-448-4325

Source: GenMark Diagnostics, Inc.

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