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# GENMARK DIAGNOSTICS, INC.

## FORM 8-K
(Current report filing)

Filed 04/20/17 for the Period Ending 04/20/17

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|---|---|
| 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 |

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# 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): April 20, 2017

# GENMARK DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

**Commission File Number: 001-34753**

| **Delaware** | **27-2053069** |
|---|---|
| (State or other jurisdiction of incorporation) | (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))

**Item 2.02. Results of Operations and Financial Condition.**

On April 20, 2017, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its preliminary financial results for the fiscal quarter ended March 31, 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 April 20, 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: April 20, 2017

/s/ Scott Mendel

Scott Mendel

Chief Financial Officer

**EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated April 20, 2017. |

Exhibit 99.1

April 20, 2017

**GenMark Achieves CE Mark for its ePlex® Blood Culture Identification Fungal Pathogen Panel**

**Reports Positive Preliminary First Quarter Revenues of $12.5 Million up 13% Versus Prior Year**
**Over 70 ePlex Customer Agreements Totaling More than 100 Analyzers in Place at the End of First Quarter**

CARLSBAD, Calif.-(BUSINESS WIRE)- GenMark Diagnostics, Inc. (Nasdaq:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced it has achieved CE Mark under the European In-Vitro Diagnostic Devices Directive (98/79/EC) for its ePlex Blood Culture Identification Fungal Pathogen (BCID-FP) Panel. BCID-FP is the first panel in the GenMark Sepsis Solution, which will also include BCID Gram-Positive and Gram-Negative panels.

“We are very pleased to bring the first of our three blood culture identification panels to the European market. Rapid diagnosis of blood stream infections can have significant impact on improving patient outcomes and reducing cost of therapy. GenMark’s approach will enable this by providing the broadest pathogen inclusivity and drug resistance markers of any multiplex molecular solution on the market today,” said Hany Massarany, President and Chief Executive Officer of GenMark.

“Fungal blood stream infections are some of the most critical conditions we face in the clinical laboratory and diagnosing them quickly and accurately has a significant positive impact on patient outcomes. The ePlex Fungal Pathogen Panel brings rapid and essential information regarding fungemia and its ease of use allows a perfect integration in the routine workflow,” stated Dr. Danièle Maubon, MD, PhD, of Grenoble Alpes University Hospital.

Information on the GenMark Sepsis Solution will be highlighted at the 27th European Congress of Clinical Microbiology and Infectious Diseases Meeting (ECCMID) in Vienna, Austria, from April 22-25, 2017, during conference poster sessions and a private customer symposium.

The company also reported preliminary first quarter 2017 revenue of $12.5 million, an increase of 13% over the prior year period. In addition, the company announced that during the quarter, it added more than 15 customer agreements. “First quarter revenue was in line with our expectations and we continue to be very pleased with the increasing customer interest in our ePlex sample-to-answer system, particularly following our submissions to FDA last quarter. We finished the first quarter with over 70 agreements totaling more than 100 ePlex analyzers, many of which have already been installed in end-user sites,” added Massarany.

**ABOUT GENMARK DIAGNOSTICS**

GenMark Diagnostics (NASDAQ: GNMK) GenMark Diagnostics 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 a compact, easy-to-use workstation 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, the timely commercialization and regulatory clearance of our ePlex system, and the availability of future financing, 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.
Hany Massarany
President/Chief Executive Officer
760-448-4325

Source: GenMark Diagnostics, Inc.

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