# 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): January 8, 2019

# 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))

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 January 8, 2019, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its preliminary financial results for the fourth quarter and fiscal year ended December 31, 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 January 8, 2019

**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: January 8, 2019

/s/ Scott Mendel

Scott Mendel

Chief Financial Officer

**EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated January 8, 2019. |

**Exhibit 99.1**

January 8, 2019

**GenMark Diagnostics Provides Preliminary Operational and Financial Results for 2018**

CARLSBAD, Calif. - GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today provided preliminary operational and financial results for the year ended December 31, 2018.

**Financial Highlights**

- Total revenue for 2018 expected to be approximately $70.8 million, representing an increase of 35% over 2017
  - ePlex® revenue for the full year 2018 expected to be approximately $37.9 million, an increase of more than 270% over 2017
- Total revenue for the fourth quarter of 2018 expected to be approximately $19.4 million, representing an increase of 21% over the fourth quarter of 2017
  - ePlex revenue for the fourth quarter of 2018 expected to be approximately $12.1 million, an increase of approximately 110% versus the fourth quarter of 2017
- Cash and investments at December 31, 2018 of approximately $45.2 million

**Operational Highlights**

- Placed 42 ePlex analyzers in the fourth quarter of 2018, finishing the year with an installed base of 354 ePlex analyzers in U.S. and European labs
- Received FDA 510(k) Market Clearance for the company's ePlex Blood Culture Identification Gram-Positive Panel (BCID-GP) and Fungal Pathogen Panel (BCID-FP)

"We delivered solid financial and operational results in the fourth quarter, to complete another exciting year for our company. We expect this strong momentum to continue in 2019, driven by the expanding installed base of our ePlex analyzers and the recent FDA clearances of our BCID panels," said Hany Massarany, President and Chief Executive Officer. "With the Gram-Positive and Fungal Pathogen Panels already cleared for marketing in the U.S., and the Gram-Negative Panel currently under review by the FDA, we expect BCID to be a strong driver of ePlex placements and revenue growth in 2019. These will continue to be significant areas of focus for our company in 2019, as will our ongoing efforts to improve ePlex gross margin," added Massarany.

These preliminary results are based on management's initial analysis of operations for the quarter and year ended December 31, 2018 and are subject to further internal review and audit by the company's external auditors. The company expects to issue full 2018 financial results and 2019 guidance in late February.

**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.

**Forward Looking Statements**

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 preliminary, unaudited financial and operational performance and the timely FDA clearance and commercialization of additional ePlex panel menu, 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 obtain regulatory clearance in the United States for our ePlex Gram-Negative BCID Panel, our preliminary 2018 financial and operational results are unaudited results based on management's current expectations and are subject to closing and year-end audit adjustments, the commercialization 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**
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