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 11, 2021**

GENMARK DIAGNOSTICS, INC.

(Exact name of registrant as specified in its Charter)

Delaware	**001-34753**	**27-2053069**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

5964 La Place Court **Carlsbad, California**	**92008**
(Address of principal executive office)	(Zip Code)

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

Not Applicable

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	GNMK	The NASDAQ Stock Market LLC

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 11, 2021, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its preliminary financial results for the fourth quarter and fiscal year ended December 31, 2020. 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) Exhibits. The exhibits shall be deemed to be filed or furnished, depending on the relevant item requiring such exhibit, in accordance with the provisions of Item 601 of Regulation S-K (17 CFR 229.601) and Instruction B.2 to this form.

Exhibit Number	Description
99.1	Press release dated January 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 11, 2021

/s/ Eric Stier

Eric Stier
Senior Vice President, General Counsel and Secretary

EXHIBITS

Exhibit Number	Description
99.1	Press release dated January 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Exhibit 99.1

January 11, 2021

GenMark Diagnostics Provides Preliminary Operational and Financial Results for 2020

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, 2020.

Financial Highlights

- Total revenue for 2020 is expected to be approximately $171 million, representing an increase of approximately 95% over 2019
  - ePlex® revenue for the full year 2020 is expected to be approximately $152 million, an increase of 155% over 2019
- Total revenue for the fourth quarter of 2020 is expected to be approximately $50 million, representing an increase of 84% over the fourth quarter of 2019
  - ePlex revenue for the fourth quarter of 2020 is expected to be approximately $45 million, an increase of 138% over the fourth quarter of 2019
- Gross margin is expected to be approximately 39% for the fourth quarter of 2020 and between 39% and 40% for the full year 2020

Operational Highlights

- Placed 70 net new ePlex analyzers in the fourth quarter of 2020, finishing the year with an installed base of 792 ePlex analyzers placed worldwide
  - ePlex installed base grew 50% year over year
- Fourth quarter annuity was approximately $220,000 per analyzer, compared to approximately $148,000 in the fourth quarter of 2019
- Increased manufacturing capacity by more than 75% versus prior year with the completion of the first of two new production lines during the quarter

“Fourth quarter demand remained very strong, driven by our ePlex RP2 and blood culture ID panels that provide broad pathogen coverage and simplified workflow with hands on time of one minute or less,” said Scott Mendel, President and Chief Executive Officer. “During the quarter, we validated the first of our two new ePlex manufacturing lines that increases our production capacity to approximately 160,000 ePlex tests per month and we remain on track to validate the second line in the very near future.”

“With multi-year contracts that include committed volumes, GenMark has created an enduring and recurring revenue stream that provides visibility to driving continued top line growth in 2021. I’m proud of the entire GenMark organization, as we remained committed to our key priorities and delivered remarkable results throughout the entire year under extraordinary circumstances,” concluded Mendel.

These preliminary results are based on management’s initial analysis of operations for the quarter and year ended December 31, 2020 and are subject to further internal review and audit by the company’s external auditors. The company expects to issue full 2020 financial results and 2021 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, expected increases to our ePlex manufacturing capacity, 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 validate additional ePlex manufacturing lines and 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 its 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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