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): **July 7, 2020**

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**

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 Global Market

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. o

Item 2.02. Results of Operations and Financial Condition

On July 7, 2020, GenMark Diagnostics, Inc. (the "Company") issued a press release announcing its preliminary financial results for the fiscal quarter ended June 30, 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) The following exhibit is furnished with this Current Report:

99.1 Press release dated July 7, 2020

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: July 7, 2020

/s/ Eric Stier

Eric Stier

Senior Vice President, General Counsel and Secretary

EXHIBITS

Exhibit Number	Description
99.1	Press release dated July 7, 2020

Exhibit 99.1

July 7, 2020

GenMark Diagnostics Provides Preliminary Financial and Operational Results for Second Quarter 2020

Second Quarter 2020 Revenue Expected to Represent Approximately 118% Year-Over-Year Growth

CARLSBAD, Calif. - GenMark Diagnostics, Inc. (NASDAQ:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today provided preliminary financial and operational results for the quarter ended June 30, 2020.

Second Quarter 2020 Financial Highlights

- Total revenue expected to be approximately $40.1 million, representing an increase of 118% over the second quarter of 2019
  - ePlex® revenue expected to be approximately $35.2 million, an increase of approximately 195% compared to the second quarter of 2019
  - Average annuity per analyzer of approximately $188,000, up 74% over the second quarter of 2019
- COVID-19 positively impacted second quarter placements and revenue
  - Approximately 90% of gross placements included interest in COVID-19 testing
  - SARS-CoV-2 consumable revenue accounted for approximately 48% of total ePlex revenue
- Gross margin expected to be approximately 38% to 39%, compared to 36% in the second quarter of 2019

Second Quarter 2020 Operational Highlights

- Placed net 71 ePlex analyzers, concluding the quarter with a global installed base of more than 650 ePlex analyzers, an increase of 48% versus the second quarter of 2019
- Submitted an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for the ePlex Respiratory Pathogen Panel 2 (RP2 Panel), one of the first rapid-result multiplex panel tests that can identify 21 respiratory pathogens, including SARS-CoV-2
- Launched RP2 Panel for U.S. commercial distribution and clinical use

“The GenMark team continued to deliver excellent progress throughout the second quarter,” said Scott Mendel, President and Chief Executive Officer. "Strong COVID-19 demand continued to drive additional ePlex placements, which provides the foundation for future recurring testing revenues across our broader menu. We were also encouraged to see a number of customers implement our RP and BCID Panels during the second quarter, including some customers that originally adopted ePlex for COVID-19 testing. In addition, we launched our RP2 Panel, which incorporates SARS-CoV-2 onto our existing syndromic panel for respiratory pathogen testing. The RP2 panel also introduces a simplified workflow, making it even easier for hospital labs to run our test.”

“I am proud of the many accomplishments we’ve made in response to the pandemic and believe that our business has been positively transformed for the long-term as a result. We remain focused on our key business priorities of driving commercial execution, continued gross margin improvement, and profitability, as well as delivering innovative solutions to address market needs," concluded Mendel.

These preliminary results are based on management's initial analysis of operations for the quarter ended June 30, 2020 and are subject to further internal review. The company expects to issue full second quarter 2020 financial results and updated 2020 guidance in early August.

About Emergency Use Authorization Status

The GenMark ePlex SARS-CoV-2 Test and ePlex RP2 Panel have been made available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of COVID-19. The EUAs for these tests are in effect for the duration of the COVID-19 emergency, unless terminated or revoked (after which the tests may no longer be used). An FDA cleared IVD should be used instead of an IVD under EUA, when applicable and available.

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 preliminary, unaudited financial and operational performance, our ability to secure enduring revenue streams extending beyond the COVID-19 pandemic, regulatory submissions and approvals, and plans and objectives of management, 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, disruptions to our supply chain, our ability to achieve our updated financial and operational performance guidance, audit adjustments to our preliminary results, our ability to successfully obtain regulatory clearance for our ePlex RP2 Panel 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 retain customers beyond the COVID-19 pandemic, 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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