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

July 7, 2020

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

CARLSBAD, Calif., July 07, 2020 (GLOBE NEWSWIRE) -- 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
Leigh Salvo
(415) 937-5404

Source: GenMark Diagnostics, Inc.