GenMark Diagnostics Reports Second Quarter 2020 Results

August 4, 2020

CARLSBAD, Calif., Aug. 04, 2020 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (Nasdaq: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the quarter ended June 30, 2020.

Second Quarter 2020 Highlights

- Total revenue of $40.1 million, an increase of 118% over the second quarter of 2019
  - ePlex® revenue of $35.2 million, an increase of approximately 195% over the second quarter of 2019
  - Average annuity per analyzer of $188,000, up 74% over the second quarter of 2019
  - COVID-19 testing drove a material increase in placements and revenue
- Gross margin of 40%, compared to 36% in the second quarter of 2019
- Cash and investments were $132.8 million as of June 30, 2020, an increase of $85.7 million over the first quarter
  - Delivered $8.0 million in positive cash flows from operating activities
  - Generated $75.4 million in net proceeds from common stock offering in May

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

"While we could not have anticipated the depth and duration of this global health crisis, our team continued to deliver on our commitments for 2020, including delivering exceptional revenue growth and continued gross margin improvement. And, for the first time in the company's history, we achieved positive cash flow. This performance reflects the tremendous demand we've seen from both existing and new customers for our ePlex platform, and our ability to address that demand in an increasingly efficient and cost effective way," said Scott Mendel, President and Chief Executive Officer. "As we enter the second half of the year, I am more confident than ever that GenMark's business has been positively transformed for the long term, and is positioned as a leading innovator in multiplex molecular diagnostic testing systems."

Guidance for Full Year 2020
GenMark increases its total revenue guidance for the full year 2020 to a range of $155 million to $165 million. This compares to the previously stated range of $120 million to $130 million.

The Company increased its global ePlex placement to 230 to 250 net new analyzers with an increased annuity per analyzer of $175,000 to $200,000.

Gross margin is expected to be in the 38% to 40% range. Operating expenses are now expected to be approximately $70 million to $75 million.

Cash usage excluding financing activities is projected to be in the range of $10 million to $15 million.

Webcast and Conference Call Information
GenMark will be hosting a conference call to discuss second quarter results in further detail on today starting at 4:30 p.m. ET. The conference call will be concurrently webcast. The link to the webcast is available on the Company website at www.genmarkdx.com under the investor relations section and will be archived for future reference. To listen to the conference call, please dial (877) 312-5847 (US/Canada) or (253) 237-1154 (International) and use the conference ID number 1067506 approximately five minutes prior to the start time.

About Emergency Use Authorization
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 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, 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.

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GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	June 30, 2020	December 31, 2019
ASSETS:		
Current Assets:		
Cash and cash equivalents	$ 82,421	$ 44,360
Short-term marketable securities	50,374	9,100
Accounts receivable, net of allowances of $1,132 and $376, respectively	17,867	16,759
Inventories, net	14,927	11,301
Prepaid expenses and other current assets	1,823	1,877
Total current assets	167,412	83,397
Property and equipment, net	19,420	20,419
Intangible assets, net	1,137	1,432
Restricted cash	1,646	758
Noncurrent operating lease right-of-use assets	4,372	4,642
Other long-term assets	1,026	825
Total assets	$ 195,013	$ 111,473
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 15,421	$ 12,249
Accrued compensation	8,609	7,493
Current operating lease liability	1,870	1,842
Other current liabilities	3,245	2,732
Total current liabilities	29,145	24,316
Long-term debt	70,189	69,145
Noncurrent operating lease liability	5,217	5,796
Other noncurrent liabilities	285	53
Total liabilities	104,836	99,310
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, $0.0001 par value; 100,000 authorized; 70,693 and 60,255 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	7	6

Additional paid-in capital	615,995	526,294
Accumulated deficit	(525,925)	(514,233)
Accumulated other comprehensive income	100	96
Total stockholders' equity	90,177	12,163
Total liabilities and stockholders' equity	$ 195,013	$ 111,473

GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Product revenue	$ 39,460	$ 18,071	$ 77,813	$ 39,282
Other revenue	626	303	1,015	625
Total revenue	40,086	18,374	78,828	39,907
Cost of revenue	24,235	11,801	46,825	27,471
Gross profit	15,851	6,573	32,003	12,436
Operating expenses:				
Sales and marketing	6,285	5,803	12,425	11,712
General and administrative	4,622	4,931	13,560	9,452
Research and development	7,637	7,749	13,716	14,092
Total operating expenses	18,544	18,483	39,701	35,256
Loss from operations	(2,693)	(11,910)	(7,698)	(22,820)
Other income (expense):				
Interest income	109	179	241	312
Interest expense	(2,037)	(1,528)	(4,128)	(2,804)
Other expense	—	(4)	(29)	(15)
Total other expense	(1,928)	(1,353)	(3,916)	(2,507)
Loss before provision for income taxes	(4,621)	(13,263)	(11,614)	(25,327)
Income tax expense	63	45	78	61
Net loss	$ (4,684)	$ (13,308)	$ (11,692)	$ (25,388)
Net loss per share, basic and diluted	$ (0.07)	$ (0.23)	$ (0.18)	$ (0.45)
Weighted average number of shares outstanding, basic and diluted	66,528	57,171	63,597	56,878
Other comprehensive loss:				
Net loss	$ (4,684)	$ (13,308)	$ (11,692)	$ (25,388)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax	10	15	(29)	9
Net unrealized gains on marketable securities, net of tax	29	6	33	8
Total other comprehensive income (loss)	39	21	4	17
Total comprehensive loss	$ (4,645)	$ (13,287)	$ (11,688)	$ (25,371)

GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Six Months Ended June 30, 2020	
	2020	2019

Operating activities:		
Net loss	$ (11,692)	$ (25,388)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,479	3,616
Net amortization (accretion) of premiums/discounts on investments	34	(98)
Amortization of deferred debt issuance costs	1,145	816
Stock-based compensation	8,048	5,711
Provision for bad debt	766	46
Non-cash inventory adjustments	850	897
Other non-cash adjustments	(49)	125
Changes in operating assets and liabilities:		
Accounts receivable	(1,866)	4,720
Inventories	(4,960)	(1,387)
Prepaid expenses and other assets	(382)	(784)
Accounts payable	3,598	(1,143)
Accrued compensation	624	(2,490)
Other current and non-current liabilities	790	(257)
Net cash provided by (used in) operating activities	385	(15,616)
Investing activities:		
Purchases of property and equipment	(1,703)	(467)
Purchases of marketable securities	(52,123)	(19,440)
Proceeds from sales of marketable securities	1,193	—
Maturities of marketable securities	9,655	10,800
Net cash used in investing activities	(42,978)	(9,107)
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	78,078	464
Principal repayment of borrowings	(33)	(35,140)
Proceeds from borrowings	—	50,000
Payments associated with debt issuance	(100)	(3,588)
Proceeds from stock option exercises	3,575	432
Net cash provided by financing activities	81,520	12,168
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	22	2
Net increase (decrease) in cash, cash equivalents, and restricted cash	38,949	(12,553)
Cash, cash equivalents, and restricted cash at beginning of year	45,118	37,044
Cash, cash equivalents, and restricted cash at end of period	$ 84,067	$ 24,491
Non-cash investing and financing activities:		
Transfer of systems to property and equipment from inventory	$ 483	$ 822
Property and equipment included in accounts payable	$ 807	$ 18
Supplemental cash flow information:		
Cash paid for income taxes, net	$ 48	$ 104
Cash paid for interest	$ 3,080	$ 1,837

GENMARK DIAGNOSTICS, INC.

UNAUDITED RECONCILIATION OF NON-GAAP FINANCIAL MEASURES

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP net loss	$ (4,684)	$ (13,308)	$ (11,692)	$ (25,388)
Nonrecurring charges:				
Severance payments and stock-based compensation resulting from reorganization[1]	—	—	566	—

Severance payments and stock-based compensation due to our former President and CEO upon his departure from the Company[2]	—	—	4,047	—
Total nonrecurring charges	—	—	4,613	—
Adjusted non-GAAP net loss	$ (4,684)	$ (13,308)	$ (7,079)	$ (25,388)
GAAP and non-GAAP weighted average shares outstanding - basic and diluted	66,528	57,171	63,597	56,878
GAAP net loss per share - basic and diluted	$ (0.07)	$ (0.23)	$ (0.18)	$ (0.45)
Nonrecurring charges:				
Severance payments and stock-based compensation resulting from reorganization	—	—	0.01	—
Severance payments and stock-based compensation due to our former President and CEO upon his departure from the Company	—	—	0.06	—
Total nonrecurring charges	—	—	0.07	—
Adjusted non-GAAP net loss per share - basic and diluted	$ (0.07)	$ (0.23)	$ (0.11)	$ (0.45)

[1] Severance payments and stock-based compensation expense resulting from the elimination of certain positions within the Company. Stock-based compensation expense resulted from the acceleration of the vesting of restricted stock units awarded to certain individuals.

[2] Severance payments and stock-based compensation expense resulting from the departure of the Company's former President and CEO. The Company will be making a $1 million severance payment to the Company's former President and CEO on October 1, 2020 and will be providing reimbursement for group health insurance premium payments pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") for 1 year following the separation date. The Company recognized $3 million in stock-based compensation expense resulting from the acceleration of the vesting of the outstanding unvested portion of restricted stock units and market-based stock units.

Use of Non-GAAP Financial Information

In addition to results reported under GAAP, we provide certain non-GAAP financial measures consisting of adjusted non-GAAP net loss and adjusted non-GAAP basic and diluted net loss per share. Non-GAAP net loss consists of the net loss reported in our Unaudited Condensed Consolidated Statement of Comprehensive Loss adjusted for nonrecurring severance payments and stock-based compensation expense from the elimination of certain positions and the departure of our former President and CEO. Adjusted non-GAAP basic and diluted net loss per share reflects the net loss per share reported in our Unaudited Condensed Consolidated Statement of Comprehensive Loss adjusted for the loss per share resulting from nonrecurring severance payments and stock-based compensation expense from the elimination of certain positions and the departure of our former President and CEO.

We believe that use of these non-GAAP financial measures can assist investors in understanding the results from our core operations by providing additional insight into the impact of nonrecurring activities on our GAAP financial measures. We believe that the use of these non-GAAP financial measures enhances the comparability of our current period results to our historical Unaudited Condensed Consolidated Financial Statements, as well as to the results of other public companies.

The use of these non-GAAP financial measures are not measurements of financial performance under GAAP and have been included solely for informational and comparative purposes. Other companies may define these non-GAAP financial measures differently and, as a result, our non-GAAP financial measures may not be directly comparable to the non-GAAP measures of other companies. We reconciled non-GAAP net loss and adjusted non-GAAP basic and diluted net loss per share to GAAP net loss and GAAP net loss per share, respectively, which we believe to be the most directly comparable GAAP financial measures. Reconciliations of non-GAAP and GAAP financial measures should be considered together with our Unaudited Condensed Consolidated Financial Statements.

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Source: GenMark Diagnostics, Inc.