



GenMark Diagnostics Reports Third Quarter 2020 Results

October 28, 2020

CARLSBAD, Calif., Oct. 28, 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 September 30, 2020.

Third Quarter 2020 Highlights

- Total revenue of \$42.6 million, an increase of 104% over the third quarter of 2019
 - ePlex[®] revenue of \$38.0 million, an increase of 187% over the third quarter of 2019
 - Average annuity per analyzer of \$193,000, up 82% over the third quarter of 2019
- Gross margin of 39%, compared to 34% in the third quarter of 2019
- Cash and investments were \$137.3 million as of September 30, 2020, an increase of \$4.5 million over June 30, 2020
 - Delivered \$6.3 million in positive cash flows from operating activities
- Placed net 70 ePlex analyzers, concluding the quarter with a global installed base of more than 720 ePlex analyzers, an increase of 47% over the third quarter of 2019
- ePlex Respiratory Pathogen Panel 2 (RP2), one of the first rapid-result multiplex panels to identify 21 respiratory pathogens, including SARS-CoV-2, received Emergency Use Authorization (EUA)
 - RP2 drove the majority of the placements and revenue for the quarter

"The GenMark team once again delivered meaningful progress on each of the strategic objectives established at the outset of this year, including another quarter of strong revenue growth, cash flow positivity, and further menu development," said Scott Mendel, President and Chief Executive Officer. "I am especially encouraged by the significant number of customers that have transitioned to ePlex RP2, which enables comprehensive diagnosis for effective patient management. These transitions are important because they include multi-year contracts that increase our highly predictable revenue stream."

Guidance for Full Year 2020

GenMark increased its total revenue guidance for the full year 2020 to a range of \$165 million to \$168 million. This compares to the previously stated range of \$155 million to \$165 million.

The Company expects to achieve the top end of both its global ePlex placement guidance of 230 to 250 net new analyzers and annuity per analyzer of \$175,000 to \$200,000.

Gross margin is expected to be in upper end of the Company's previously stated range of 38% to 40%. Operating expenses are expected to be at the high end of the Company's previously stated range of \$70 million to \$75 million.

Cash usage excluding financing activities for the year continues to be projected in the range of \$10 million to \$15 million.

Webcast and Conference Call Information

GenMark will be hosting a conference call to discuss third quarter results in further detail 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 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 manufacturing operations and/or supply chain, our ability to achieve our updated financial and operational performance guidance, our ability to successfully obtain regulatory clearance for ePlex RP2 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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GENMARK DIAGNOSTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	September 30, 2020	December 31, 2019
ASSETS:		
Current Assets:		
Cash and cash equivalents	\$ 57,809	\$ 44,360
Short-term marketable securities	79,468	9,100
Accounts receivable, net of allowances of \$511 and \$376, respectively	16,231	16,759
Inventories, net	19,570	11,301
Prepaid expenses and other current assets	2,836	1,877
Total current assets	175,914	83,397
Property and equipment, net	26,210	20,419
Intangible assets, net	989	1,432
Restricted cash	1,646	758
Noncurrent operating lease right-of-use assets	8,845	4,642
Other long-term assets	986	825
Total assets	\$ 214,590	\$ 111,473
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 21,241	\$ 12,249
Accrued compensation	13,074	7,493
Current operating lease liability	2,741	1,842
Other current liabilities	3,614	2,732
Total current liabilities	40,670	24,316
Long-term debt	70,743	69,145
Noncurrent operating lease liability	8,912	5,796
Other noncurrent liabilities	308	53
Total liabilities	120,633	99,310
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 71,286 and 60,255 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	7	6
Additional paid-in capital	622,951	526,294
Accumulated deficit	(529,153)	(514,233)

Accumulated other comprehensive income	152	96
Total stockholders' equity	93,957	12,163
Total liabilities and stockholders' equity	\$ 214,590	\$ 111,473

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Revenue:				
Product revenue	\$ 41,985	\$ 20,659	\$ 119,798	\$ 59,941
Other revenue	661	259	1,676	884
Total revenue	42,646	20,918	121,474	60,825
Cost of revenue	26,103	13,868	72,928	41,339
Gross profit	16,543	7,050	48,546	19,486
Operating expenses:				
Sales and marketing	4,979	6,279	17,404	17,991
General and administrative	5,367	4,765	18,927	14,217
Research and development	7,463	6,294	21,179	20,386
Total operating expenses	17,809	17,338	57,510	52,594
Loss from operations	(1,266)	(10,288)	(8,964)	(33,108)
Other income (expense):				
Interest income	81	126	322	438
Interest expense	(2,073)	(1,527)	(6,201)	(4,331)
Other income (expense)	13	(19)	(16)	(34)
Total other expense	(1,979)	(1,420)	(5,895)	(3,927)
Loss before provision for income taxes	(3,245)	(11,708)	(14,859)	(37,035)
Income tax expense (benefit)	(17)	(33)	61	28
Net loss	\$ (3,228)	\$ (11,675)	\$ (14,920)	\$ (37,063)
Net loss per share, basic and diluted	\$ (0.05)	\$ (0.20)	\$ (0.23)	\$ (0.65)
Weighted average number of shares outstanding, basic and diluted	71,103	57,718	66,117	57,161
Other comprehensive loss:				
Net loss	\$ (3,228)	\$ (11,675)	\$ (14,920)	\$ (37,063)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax	56	(46)	27	(37)
Net unrealized gain (loss) on marketable securities, net of tax	(4)	—	29	8
Total other comprehensive income (loss)	52	(46)	56	(29)
Total comprehensive loss	\$ (3,176)	\$ (11,721)	\$ (14,864)	\$ (37,092)

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

	Nine Months Ended	
	September 30, 2020	
	2020	2019
Operating activities:		
Net loss	\$ (14,920)	\$ (37,063)

Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,439	5,393
Net amortization (accretion) of premiums/discounts on investments	138	(134)
Amortization of deferred debt issuance costs	1,699	1,266
Stock-based compensation	10,474	8,840
Provision for bad debt, net of recoveries	156	93
Non-cash inventory adjustments	1,238	1,653
Other non-cash adjustments	71	175
Changes in operating assets and liabilities:		
Accounts receivable	376	993
Inventories	(10,156)	(5,471)
Prepaid expenses and other assets	(1,076)	(857)
Accounts payable	7,382	345
Accrued compensation	4,862	(406)
Operating lease liabilities	(188)	—
Other current and non-current liabilities	1,176	(398)
Net cash provided by (used in) operating activities	6,671	(25,571)
Investing activities:		
Purchases of property and equipment	(7,874)	(1,193)
Purchases of marketable securities	(89,340)	(26,735)
Proceeds from sales of marketable securities	1,193	—
Maturities of marketable securities	17,670	26,880
Net cash used in investing activities	(78,351)	(1,048)
Financing activities:		
Proceeds from issuance of common stock, net of offering costs	78,079	2,837
Principal repayment of borrowings	(45)	(35,070)
Proceeds from borrowings	—	50,000
Payments associated with debt issuance	(100)	(3,588)
Proceeds from stock option exercises	8,105	432
Net cash provided by financing activities	86,039	14,611
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(22)	30
Net increase (decrease) in cash, cash equivalents, and restricted cash	14,337	(11,978)
Cash, cash equivalents, and restricted cash at beginning of year	45,118	37,044
Cash, cash equivalents, and restricted cash at end of period	\$ 59,455	\$ 25,066
Non-cash investing and financing activities:		
Transfer of systems to property and equipment from inventory	\$ 649	\$ 1,492
Property and equipment included in accounts payable	\$ 2,843	\$ 147
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ 4,689	\$ —
Supplemental cash flow information:		
Cash paid for income taxes, net	\$ 94	\$ 85
Cash paid for interest	\$ 4,611	\$ 2,890

GENMARK DIAGNOSTICS, INC.
UNAUDITED RECONCILIATION OF NON-GAAP FINANCIAL MEASURES
(In thousands)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
GAAP net loss	\$ (3,228)	\$ (11,675)	\$ (14,920)	\$ (37,063)
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	\$ (3,228)	\$ (11,675)	\$ (10,307)	\$ (37,063)

GAAP and non-GAAP weighted average shares outstanding - basic and diluted	71,103	57,718	66,117	57,161
GAAP net loss per share - basic and diluted	\$ (0.05)	\$ (0.20)	\$ (0.23)	\$ (0.65)
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	\$ (0.05)	\$ (0.20)	\$ (0.16)	\$ (0.65)

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 made 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.



Source: GenMark Diagnostics, Inc.