



GenMark Diagnostics Reports Fourth Quarter and Full Year 2020 Results

February 25, 2021

CARLSBAD, Calif., Feb. 25, 2021 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (Nasdaq: GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the fiscal year and quarter ended December 31, 2020.

Full Year 2020 Financial Highlights

- Total revenue of \$171.6 million, an increase of 95% over 2019
 - ePlex[®] revenue of \$152.6 million, an increase of 155% over 2019
- Gross margin of 40%, compared to 32% in 2019
- Cash and investments were \$128.2 million as of December 31, 2020
 - Delivered \$6.1 million in positive cash flows from operating activities

Fourth Quarter 2020 Financial Highlights

- Total revenue of \$50.1 million, an increase of 84% over the fourth quarter of 2019
 - ePlex[®] revenue of \$45.4 million, an increase of 138% over the fourth quarter of 2019
- Gross margin of 39%, compared to 34% in the fourth quarter of 2019

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 worldwide
 - ePlex installed base grew 50% year over year
- Average annuity per analyzer of \$220,000, compared to \$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

"2020 was truly a transformational year for GenMark both financially and operationally. Our growth would not have been possible without the tremendous efforts of our team coming together to respond to a rapidly spreading disease - delivering innovative R&D and strong commercial execution. Our global ePlex installed base grew 50% year-over-year and builds on a strong foundation of enduring and predictable revenue," said Scott Mendel, President and Chief Executive Officer.

"Our priorities in 2021 include increased adoption of our BCID and RP panels, as well as driving further market penetration for our differentiated ePlex platform. We are also focused on delivering financial execution, specifically driving revenue growth and improving margins that further accelerate cash flow positivity. Lastly, we plan to increase investment in innovation, including enhancing current panels, completing new panels and investing in longer term advanced technology development."

Guidance for Full Year 2021

GenMark expects revenue for the full year 2021 in the range of \$188 million to \$198 million, which represents growth of 10% to 15% over 2020.

Global ePlex placements are expected to range from 200 to 220 net new analyzers with annuity per analyzer between \$175,000 and \$190,000.

Gross margin is expected to be in the range of 44% to 46% and operating expenses are expected to be approximately \$85 million to \$90 million.

Excluding financing activities, cash usage is projected in the range of \$10 million to \$15 million.

Webcast and Conference Call Information

GenMark will be hosting a conference call to discuss fourth 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 6957136 approximately five minutes prior to the start time.

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 2021 financial and operational performance, 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 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.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands except par value)

	As of December 31,	
	2020	2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 40,572	\$ 44,360
Short-term marketable securities	87,582	9,100
Accounts receivable, net of allowances of \$372 and \$376, respectively	20,790	16,759
Inventories, net	21,323	11,301
Prepaid expenses and other current assets	2,695	1,877
Total current assets	172,962	83,397
Property and equipment, net	38,362	20,419
Intangible assets, net	841	1,432
Restricted cash	1,646	758
Operating lease right-of-use assets	8,676	4,642
Other long-term assets	1,047	825
Total assets	\$ 223,534	\$ 111,473
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 23,071	\$ 12,249
Accrued compensation	12,716	7,493
Current operating lease liability	3,093	1,842
Other current liabilities	5,250	2,732
Total current liabilities	44,130	24,316
Long-term debt	71,297	69,145
Noncurrent operating lease liability	12,749	5,796
Other noncurrent liabilities	1,160	53
Total liabilities	129,336	99,310
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 71,960 and 60,255 shares issued and outstanding at December 31, 2020 and 2019, respectively	7	6
Additional paid-in capital	626,816	526,294
Accumulated deficit	(532,877)	(514,233)
Accumulated other comprehensive income	252	96
Total stockholders' equity	94,198	12,163
Total liabilities and stockholders' equity	\$ 223,534	\$ 111,473

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Revenue				
Product revenue	\$ 49,350	\$ 26,880	\$ 169,148	\$ 86,821
Other revenue	730	316	2,406	1,200
Total revenue	50,080	27,196	171,554	88,021
Cost of revenue	30,682	18,079	103,610	59,418
Gross profit	19,398	9,117	67,944	28,603
Operating expenses				
Sales and marketing	5,760	6,127	23,164	24,118
General and administrative	6,645	4,942	25,572	19,159
Research and development	9,080	6,754	30,259	27,140
Total operating expenses	21,485	17,823	78,995	70,417
Operating loss	(2,087)	(8,706)	(11,051)	(41,814)
Other income (expense)				
Interest income	64	74	386	512
Interest expense	(1,706)	(1,630)	(7,907)	(5,961)
Other income (expense)	25	11	9	(23)
Total other expense	(1,617)	(1,545)	(7,512)	(5,472)
Loss before income taxes	(3,704)	(10,251)	(18,563)	(47,286)
Income tax expense	20	36	81	64
Net loss	\$ (3,724)	\$ (10,287)	\$ (18,644)	\$ (47,350)
Net loss per share—basic and diluted	\$ (0.05)	\$ (0.17)	\$ (0.28)	\$ (0.82)
Weighted average number of shares outstanding—basic and diluted	71,781	58,915	67,541	57,603
Other comprehensive income				
Net loss	\$ (3,724)	\$ (10,287)	\$ (18,644)	\$ (47,350)
Foreign currency translation adjustments, net of tax	120	48	147	11
Net unrealized gain (loss) on marketable securities, net of tax	(20)	(3)	9	5
Total other comprehensive income	100	45	156	16
Total comprehensive loss	\$ (3,624)	\$ (10,242)	\$ (18,488)	\$ (47,334)

GENMARK DIAGNOSTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	For the years ended December 31,		
	2020	2019	2018
Operating activities			
Net loss	\$ (18,644)	\$ (47,350)	\$ (50,500)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities			
Depreciation and amortization	7,066	7,268	7,088
Net amortization (accretion) of premiums/discounts on investments	261	(133)	(142)
Amortization of deferred debt issuance costs	2,253	1,740	938
Stock-based compensation	12,796	12,046	11,697
Provision for bad debt, net of recoveries	17	338	23
Non-cash inventory adjustments	2,319	2,631	1,426
Other non-cash adjustments	360	537	15
Changes in operating assets and liabilities			
Accounts receivable	(4,105)	(5,584)	(878)
Inventories	(12,478)	(6,534)	(2,414)
Prepaid expenses and other assets	(858)	(750)	854

Accounts payable	5,224	1,501	(1,389)
Accrued compensation	4,945	(885)	1,059
Operating lease right-of-use assets and lease liabilities	4,170	—	—
Other current and non-current liabilities	2,808	249	(289)
Net cash provided by (used in) operating activities	6,134	(34,926)	(32,512)
Investing activities			
Purchases of property and equipment	(17,776)	(2,092)	(2,575)
Purchases of marketable securities	(114,186)	(32,135)	(29,778)
Proceeds from sales of marketable securities	1,193	—	—
Maturities of marketable securities	34,260	32,055	66,300
Net cash provided by (used in) investing activities	(96,509)	(2,172)	33,947
Financing activities			
Proceeds from issuance of common stock, net of offering costs	78,659	13,447	1,061
Principal repayment of borrowings	(57)	(35,093)	(92)
Proceeds from borrowings	—	70,000	7,098
Payments associated with debt issuance	(100)	(3,638)	(20)
Proceeds from stock option exercises	9,068	457	22
Net cash provided by financing activities	87,570	45,173	8,069
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(95)	(1)	28
Net increase (decrease) in cash, cash equivalents, and restricted cash	(2,900)	8,074	9,532
Cash, cash equivalents, and restricted cash at beginning of year	45,118	37,044	27,512
Cash, cash equivalents, and restricted cash at end of year	\$ 42,218	\$ 45,118	\$ 37,044
Non-cash investing and financing activities			
Transfer of systems to property and equipment from inventory	\$ 137	\$ 2,846	\$ 1,689
Property and equipment included in accounts payable	\$ 6,832	\$ 1,234	\$ 372
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ 4,689	\$ —	\$ —
Supplemental cash flow information			
Cash paid for interest, net	\$ 5,684	\$ 3,946	\$ 2,028
Cash paid for income taxes, net	\$ 91	\$ 155	\$ 165

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
GAAP net loss	\$ (3,724)	\$ (10,287)	\$ (18,644)	\$ (47,350)
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	\$ (3,724)	\$ (10,287)	\$ (14,031)	\$ (47,350)
GAAP and non-GAAP weighted average shares outstanding—basic and diluted				
	71,781	58,915	67,541	57,603
GAAP net loss per share—basic and diluted				
	\$ (0.05)	\$ (0.17)	\$ (0.28)	\$ (0.82)
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)	\$ (0.17)	\$ (0.21)	\$ (0.82)

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.