



GenMark Diagnostics Reports First Quarter 2019 Results

April 30, 2019

CARLSBAD, Calif., April 30, 2019 (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 March 31, 2019.

Highlights

- Recognized total revenue of \$21.5 million
 - ePlex revenues of \$15.7 million represented 73% of total revenue
 - ePlex revenues grew 31% compared to the prior year period
- Placed 39 net new ePlex analyzers, expanding the global installed base to 393 placements
 - ePlex installed base grew 72% compared to the prior year period
- Increased gross margin to 27%, a 700 basis point improvement over the prior year period
- Received FDA 510(k) clearance for ePlex Blood Culture Identification Gram-Negative Panel, completing the Company's suite of three Blood Culture Identification Panels
- Expanded commercial team in North America with the addition of Michael Harkins as SVP of Sales and transition of Michael Gleeson to SVP of Corporate and Strategic Accounts

"We achieved strong first quarter results across our key business priorities, including ePlex placements, revenue growth and gross margin improvement. Our commercial teams delivered year-over-year growth in both total revenue and ePlex revenue, even when compared to the exceptionally severe flu season we experienced in the 1st quarter of 2018. We also saw improvement in our manufacturing and cost efficiencies which drove higher ePlex gross margin in the quarter. This is especially encouraging given the significant growth of ePlex as a percentage of our total revenue," said Hany Massarany, President and Chief Executive Officer. "Menu expansion continues to be a top priority and we were delighted to receive FDA clearance for our third BCID panel. We believe that the strength of our Respiratory Pathogen panel, now combined with our full suite of BCID panels, will further differentiate ePlex as the platform of choice in molecular testing."

First Quarter Financial Results

Revenue was \$21.5 million in the first quarter of 2019, an increase of 4% versus \$20.6 million in the first quarter of 2018. Gross profit was \$5.9 million, or 27% of revenue, compared with \$4.2 million, or 20% of revenue in the same period of 2018.

Operating expenses for the first quarter of 2019 were \$16.8 million compared to \$15.0 million in the same period of 2018. The increase was largely due to additional spend on R&D related to ePlex menu development.

Loss per share was \$0.21 for the first quarter of 2019, compared to a \$0.21 loss per share in the first quarter of 2018.

Cash and investments were \$48.4 million as of March 31, 2019.

Guidance for Full Year 2019

GenMark continues to expect total revenue for the full year 2019 to be in the range of \$85 million to \$90 million.

Global ePlex placements are expected to range from 170 to 190 net new analyzers with an annuity per analyzer of \$135,000 to \$145,000. The ePlex platform is expected to reach 75% of total 2019 revenue, representing 70% year-over-year growth in ePlex revenues.

Gross margin is expected to be in the 28% to 30% range and operating expenses are expected to be approximately \$65 million to \$70 million.

Cash usage is projected to decline year-over-year to \$25 million to \$30 million.

Webcast and Conference Call Information

GenMark will be hosting a conference call to discuss first quarter results in further detail on Tuesday, April 30, 2019 starting at 4:30 p.m. ET. The conference call will be concurrently webcast. The link to the webcast will be available on the GenMark Diagnostics, Inc. 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 4595526 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 the Company's future

operating results and financial position. Such statements, including, but not limited to, those regarding its future financial performance, plans and objectives of management, and the timely and effective commercialization and clinical impact of the Company's ePlex system, are all subject to risks and uncertainties that could cause actual results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, GenMark's ability to successfully 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, the Company's ability to successfully expand sales of its product offerings outside the United States, and third-party payor reimbursement to its customers, as well as other risks and uncertainties described under the "Risk Factors" in GenMark's public filings with the Securities and Exchange Commission. The Company assumes 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)

	March 31, 2019	December 31, 2018
ASSETS:		
Current Assets:		
Cash and cash equivalents	\$ 35,304	\$ 36,286
Short-term marketable securities	13,118	8,882
Accounts receivable, net of allowances of \$75 and \$75, respectively	9,168	11,534
Inventories	9,391	10,244
Current operating lease right-of-use assets	1,260	—
Prepaid expenses and other current assets	1,396	1,483
Total current assets	69,637	68,429
Property and equipment, net	19,927	21,070
Intangible assets, net	1,875	2,023
Restricted cash	758	758
Noncurrent operating lease right-of-use assets	3,734	—
Other long-term assets	729	701
Total assets	\$ 96,660	\$ 92,981
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 8,508	\$ 9,886
Accrued compensation	5,111	7,358
Current operating lease liability	1,801	—
Other current liabilities	2,321	3,043
Total current liabilities	17,741	20,287
Deferred rent		2,996
Long-term debt	47,821	36,042
Noncurrent operating lease liability	6,591	—
Other noncurrent liabilities	70	109
Total liabilities	72,223	59,434
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 57,026 and 56,240 shares issued and outstanding, respectively	6	6
Additional paid-in capital	503,318	500,344
Accumulated deficit	(478,963) (466,883
Accumulated other comprehensive income	76	80
Total stockholders' equity	24,437	33,547
Total liabilities and stockholders' equity	\$ 96,660	\$ 92,981

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands, except per share data)

	Three Months Ended	
	March 31,	
	2019	2018
Revenue:		
Product revenue	\$ 21,371	\$ 20,576
License and other revenue	162	69
Total revenue	21,533	20,645
Cost of revenue	15,670	16,480
Gross profit	5,863	4,165
Operating expenses:		
Sales and marketing	5,909	5,402
General and administrative	4,521	4,133
Research and development	6,343	5,420
Total operating expenses	16,773	14,955
Loss from operations	(10,910)	(10,790)
Other income (expense):		
Interest income	133	187
Interest expense	(1,276)	(788)
Other income (expense)	(11)	(12)
Total other income (expense)	(1,154)	(613)
Loss before provision for income taxes	(12,064)	(11,403)
Income tax expense	16	20
Net loss	\$ (12,080)	\$ (11,423)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.21)
Weighted average number of shares outstanding, basic and diluted	56,581	55,205
Other comprehensive loss:		
Net loss	\$ (12,080)	\$ (11,423)
Other comprehensive income/(loss):		
Foreign currency translation adjustments, net of tax	(6)	34
Net unrealized gains (losses) on marketable securities, net of tax	2	8
Total other comprehensive income/(loss)	(4)	42
Total comprehensive loss	\$ (12,084)	\$ (11,381)

See accompanying notes to unaudited condensed consolidated financial statements.

GENMARK DIAGNOSTICS, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended	
	March 31,	
	2019	2018
Operating activities:		
Net loss	\$ (12,080)	\$ (11,423)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,812	1,740
Net amortization/(accretion) of premiums/discounts on investments	(21)	(42)
Amortization of deferred debt issuance costs	366	290
Stock-based compensation	2,544	2,724
Non-cash inventory adjustments	634	449
Other non-cash adjustments	(16)	84
Changes in operating assets and liabilities:		
Accounts receivable	2,355	2,566
Inventories	(131)	(526)

Prepaid expenses and other assets	—	760	
Accounts payable	(1,043) (1,361)
Accrued compensation	(2,475) (992)
Other current and non-current liabilities	(126) (321)
Net cash used in operating activities	(8,181) (6,052)
Investing activities:			
Purchases of property and equipment, net	(333) (465)
Purchases of marketable securities	(12,014) (7,900)
Maturities of marketable securities	7,800	18,000	
Net cash provided by (used in) investing activities	(4,547) 9,635	
Financing activities:			
Principal repayment of borrowings	(35,116) (22)
Proceeds from borrowings	50,000	—	
Payments associated with debt issuance	(3,588) (20)
Proceeds from stock option exercises	430	17	
Net cash provided by (used in) financing activities	11,726	(25)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	20	(34)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(982) 3,524	
Cash, cash equivalents, and restricted cash at beginning of year	37,044	27,512	
Cash, cash equivalents, and restricted cash at end of period	\$ 36,062	\$ 31,036	
Non-cash investing and financing activities:			
Transfer of systems (from) to property and equipment into (from) inventory	\$ 351	\$ 569	
Property and equipment included in accounts payable	\$ 36	\$ 147	
Supplemental cash flow information:			
Cash paid for income taxes, net	\$ 44	\$ 33	
Cash paid for interest	\$ 761	\$ 508	

See accompanying notes to unaudited condensed consolidated financial statements.



Source: GenMark Diagnostics, Inc.