

GenMark Diagnostics Reports Second Quarter 2018 Results

July 30, 2018

CARLSBAD, Calif., July 30, 2018 (GLOBE NEWSWIRE) -- GenMark Diagnostics, Inc. (Nasdaq:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the second quarter ended June 30, 2018.

Highlights

- Recognized revenues of \$14.9 million, an increase of 21% over the prior year period
- Placed 39 net new ePlex analyzers, expanding the global installed base to 267 placements
- Submitted the ePlex BCID Gram Positive panel to the FDA
- · Completed clinical testing for FDA submission of the ePlex BCID Gram Negative panel
- Commenced clinical study for FDA submission of the ePlex Fungal Pathogen panel

"Our second quarter results reflect solid execution on our strategic priorities of growth through ePlex commercialization and menu expansion, as well as improving manufacturing efficiencies. Top line performance was largely driven by strong ePlex placements and demand for our respiratory pathogen test cartridges. We also submitted to the FDA the first of three blood culture identification panels being developed on our ePlex system, which was a significant milestone for the company. We expect FDA submission of the remaining two blood culture panels in the third and fourth quarters of this year, as previously communicated," said Hany Massarany, President and Chief Executive Officer. "Based on this momentum and our continued focus on commercial and operational execution, I am confident we will achieve our goals for 2018 and beyond."

Second Quarter Financial Results

Revenue was \$14.9 million in the second quarter of 2018, an increase of 21% versus \$12.4 million in the second quarter of 2017. Gross profit was \$4.4 million, or 30% of revenue, compared with \$4.9 million, or 40% of revenue in the same period of 2017, reflecting the increased proportion of ePlex revenues in the quarter versus prior year.

Operating expenses for the second quarter of 2018 were \$20.2 million compared to \$22.2 million in the same period for 2017. The decrease was largely due to reduced ePlex development expenses.

Loss per share was \$0.30 per share for the second quarter of 2018, compared to a \$0.37 loss per share in the second quarter of 2017.

The Company ended the quarter with \$55.2 million in cash and investments, reflecting the impact of reductions in operating expenses and efforts to minimize working capital needs.

Guidance for Full Year 2018

GenMark is reconfirming 2018 revenue guidance of \$68 to \$72 million. Gross margin is expected to be in the 30% range. The Company continues to expect ePlex placements of 140-170 net new analyzers, and an annuity per ePlex placement in the \$100,000 to \$120,000 range.

Webcast and Conference Call Information

GenMark will be hosting a conference call to discuss second quarter results in further detail on Monday, July 30, 2018 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 4473539 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 future financial performance, regulatory submissions and approvals, and the timely and effective commercialization and clinical impact of our ePlex system, 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, our 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, 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)

	June 30, 2018	December 31, 2017	
ASSETS:			
Current Assets:			
Cash and cash equivalents	\$ 28,891	\$ 26,754	
Short-term marketable securities	26,358	45,236	
Accounts receivable, net of allowances of \$86 and \$2,754, respectively	7,144	10,676	
Inventories	8,828	10,949	
Prepaid expenses and other current assets	1,912	2,216	
Total current assets	73,133	95,831	
Property and equipment, net	21,159	22,581	
Intangible assets, net	2,327	2,624	
Restricted cash	758	758	
Other long-term assets	522	505	
Total assets	\$ 97,899	\$ 122,299	
LIABILITIES AND STOCKHOLDERS' EQUITY:			
Current liabilities:			
Accounts payable	\$ 9,219	\$ 11,171	
Accrued compensation	4,872	5,419	
Current portion of long-term debt	19,009	7,927	
Other current liabilities	2,710	3,226	
Total current liabilities	35,810	27,743	
Deferred rent	2,715	3,059	
Long-term debt	9,579	20,099	
Other noncurrent liabilities	146	241	
Total liabilities	48,250	51,142	
Stockholders' equity:			
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	_	_	
Common stock, \$0.0001 par value; 100,000 authorized; 55,753 and 55,066 shares issued outstanding, respectively	and 6	6	
Additional paid-in capital	493,921	487,525	
Accumulated deficit	(444,329) (416,383)
Accumulated other comprehensive income	51	9	,
Total stockholders' equity	49,649	71,157	
Total liabilities and stockholders' equity	\$ 97,899	\$ 122,299	
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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,		
	2018	2017	2018	2017	
Revenue:					
Product revenue	\$ 14,867	\$ 12,291	\$ 35,443	\$ 24,761	
License and other revenue	74	68	143	133	
Total revenue	14,941	12,359	35,586	24,894	
Cost of revenue	10,527	7,475	27,007	13,827	
Gross profit	4,414	4,884	8,579	11,067	
Operating expenses:					

Sales and marketing	5,187		5,159		10,589		9,853	
General and administrative	4,547		3,978		8,680		7,988	
Research and development	10,482		13,014		15,902		24,049	
Total operating expenses	20,216		22,151		35,171		41,890	
Loss from operations	(15,802)	(17,267)	(26,592)	(30,823)
Other income (expense):								
Interest income	202		54		389		106	
Interest expense	(797)	(755)	(1,585)	(1,261)
Other income (expense)	(90)	56		(102)	151	
Total other income (expense)	(685)	(645)	(1,298)	(1,004)
Loss before provision for income taxes	(16,487)	(17,912)	(27,890)	(31,827)
Income tax expense	34		77		54		78	
Net loss	\$ (16,521)	\$ (17,989)	\$ (27,944)	\$ (31,905)
Net loss per share, basic and diluted	\$ (0.30)	\$ (0.37)	\$ (0.50)	\$ (0.67)
Weighted average number of shares outstanding, basic and diluted	55,547		48,067		55,377		47,460	
Other comprehensive loss:								
Net loss	\$ (16,521)	\$ (17,989)	\$ (27,944)	\$ (31,905)
Other comprehensive income/(loss):								
Foreign currency translation adjustments, net of tax	14		3		(20)	94	
Net unrealized gains (losses) on marketable securities, net of tax	14		1		22		(15)
Total other comprehensive income/(loss)	28		4		2		79	
Total comprehensive loss	\$ (16,493)	\$ (17,985)	\$ (27,942)	\$ (31,826)

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

	Six Months Ended June 30, 2018		2017	
Operating activities:				
Net loss	\$ (27,944)	\$ (31,905)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	3,507		2,454	
Net amortization/(accretion) of premiums/discounts on investments	(78)	30	
Amortization of deferred debt issuance costs	583		493	
Stock-based compensation	5,799		5,602	
Provision for bad debt	34		32	
Non-cash inventory adjustments	809		565	
Other non-cash adjustments	(13)	(123)
Changes in operating assets and liabilities:				
Accounts receivable	3,501		1,795	
Inventories	353		(2,563)
Prepaid expenses and other assets	340		(119)
Accounts payable	(1,853)	(3,134)
Accrued compensation	(853)	(1,170)
Other current and non-current liabilities	(622)	(124)
Net cash used in operating activities	(16,437)	(28,167)
Investing activities:				
Purchases of property and equipment, net	(924)	(2,535)
Purchases of marketable securities	(23,622)	(10,496)
Proceeds from sales of marketable securities	_		13,896	
Maturities of marketable securities	42,600		4,100	
Net cash provided by investing activities	18,054		4,965	
Financing activities:				
Proceeds from issuance of common stock	535		86,835	
Costs incurred in conjunction with public offering	_		(5,171)
Principal repayment of borrowings	(45)	(964)
Proceeds from borrowings	_		15,000	
Payments associated with debt issuance	(20)	(187)

Proceeds from stock option exercises	22	170	
Net cash provided by financing activities	492	95,683	
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	28	(13)
Net increase in cash, cash equivalents, and restricted cash	2,137	72,468	
Cash, cash equivalents, and restricted cash at beginning of year	27,512	16,717	
Cash, cash equivalents, and restricted cash at end of period	\$ 29,649	\$ 89,185	
Non-cash investing and financing activities:			
Transfer of systems (from) to property and equipment into (from) inventory	\$ 956	\$ (1,534)
Property and equipment included in accounts payable	\$ 168	\$ 713	
Intellectual property acquisitions included in other current liabilities	\$ —	\$ 500	
Supplemental cash flow information:			
Cash paid for income taxes, net	\$ 113	\$ 54	
Cash paid for interest	\$ 1,003	\$ 574	



Source: GenMark Diagnostics, Inc.