



February 28, 2017

GenMark Diagnostics Reports Fourth Quarter and Full Year 2016 Results

Fourth Quarter Revenue Increased 13% Versus Prior Year to \$14.9 million

Full Year Revenue Grew by 25% to \$49.3 million

Submitted FDA 510(k) Applications for ePlex Instrument and Respiratory Pathogen Panel

Ended 2016 with More Than 55 Customer Agreements, Representing Over 85 ePlex Instruments

CARLSBAD, Calif.--(BUSINESS WIRE)-- GenMark Diagnostics, Inc. (Nasdaq:GNMK), a leading provider of automated, multiplex molecular diagnostic testing systems, today announced financial results for the fourth quarter and year ended December 31, 2016.

Revenue for the fourth quarter of 2016 was \$14.9 million, an increase of 13% over the prior year period. Full year 2016 revenue grew to \$49.3 million, an increase of 25% versus 2015. Annuity per XT-8 analyzer was \$86 thousand in the fourth quarter and approximately \$74 thousand per analyzer over the last 4 quarters.

Gross profit for the fourth quarter was \$8.6 million, or 58% of revenue, compared with \$8.5 million, or 64% of revenue in the same period of 2015. Full year 2016 gross profit was \$29.6 million, or 60% of revenue.

"Last year we delivered strong results including growing our revenues by 25%, as well as successfully launching ePlex in Europe and ending the year with more than 55 customer agreements. We also completed the necessary FDA studies and submissions for the [ePlex system](#) and [RP panel](#)," said [Hany Massarany](#), President and Chief Executive Officer of GenMark. "2017 will be a pivotal year for our company, as we successfully launch ePlex in the USA and drive its continued adoption and business success in the European and US markets. Based on multiple internal and external studies with several thousand samples, we are very pleased with the performance of all three ePlex Blood Culture ID panels, which we expect to launch in Europe during the second quarter and submit to the FDA later this year," added Massarany.

Operating expenses for the fourth quarter of 2016 were \$20.7 million compared to \$17.0 million in the same period for 2015. The increase was mainly driven by Research and Development expenses as the Company continues to develop assays on the ePlex system. For the full year, 2016 operating expenses were \$78.6 million, an increase of \$12.9 million over 2015 primarily driven by Research and Development investment in ePlex.

Loss per share was \$0.27 per share for the fourth quarter of 2016 compared to a loss of \$0.21 per share in the same period of 2015. For the full year 2016, loss per share was \$1.15.

The Company ended the year with \$41.6 million in cash and cash equivalents and intends to continue utilizing its cash balances to invest in the global commercialization of the ePlex system. The Company's existing debt facility can provide up to an additional \$20 million to support the launch of ePlex internationally as well as domestically.

Business Outlook

For full year 2017, the Company expects revenue in the range of \$65 to \$70 million and gross margin in the range of 48-52%.

The Company will be hosting a conference call to discuss fourth quarter results in further detail and release 2017 guidance on Tuesday, February 28, 2017 starting at 4:30 p.m. Eastern Time. 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 51141106 approximately five minutes prior to the start time.

ABOUT GENMARK DIAGNOSTICS

[GenMark Diagnostics](#) (NASDAQ: GNMK) is a leading provider of automated, multiplex molecular diagnostic testing systems that detect and measure DNA and RNA targets to diagnose disease and optimize patient treatment. Utilizing GenMark's proprietary eSensor® detection technology, GenMark's eSensor XT-8® system is designed to support a broad range of molecular diagnostic tests with a compact, easy-to-use workstation and self-contained, disposable test cartridges. The eSensor detection technology is also incorporated into GenMark's True Sample-to-Answer System, ePlex®. 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, the timely commercialization and regulatory clearance of our ePlex system, and the availability of future financing, 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.

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

	As of December 31,	
	2016	2015
Current assets		
Cash and cash equivalents	\$ 15,959	\$ 35,385
Marketable securities	25,607	10,080
Accounts receivable, net of allowances of \$2,740 and \$2,727, respectively	9,048	6,847
Inventories	6,633	3,054
Prepaid expenses and other current assets	1,202	591
Total current assets	58,449	55,957
Non-current assets		
Property and equipment, net	18,268	11,396
Intangible assets, net	2,670	2,376
Restricted cash	758	758
Other long-term assets	179	180
Total assets	\$ 80,324	\$ 70,667
Current liabilities		
Accounts payable	\$ 8,703	\$ 4,376
Accrued compensation	5,650	3,861
Loan payable	7,935	(373)
Other current liabilities	4,133	2,725
Total current liabilities	26,421	10,589
Long-term liabilities		
Deferred rent	3,652	1,257
Long-term debt	11,880	9,890
Other non-current liabilities	220	334
Total liabilities	42,173	22,070
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 46,554 and 42,551 shares issued and outstanding as of December 31, 2016 and December 31, 2015, respectively	4	4
Additional paid-in capital	393,322	353,233

Accumulated deficit	(355,270)	(304,669)
Accumulated other comprehensive income (loss)	95	29
Total stockholders' equity	<u>38,151</u>	<u>48,597</u>
Total liabilities and stockholders' equity	<u>\$ 80,324</u>	<u>\$ 70,667</u>

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

	Three Months Ended December 31,		Twelve Months ended December 31,	
	2016	2015	2016	2015
Revenue	<i>(unaudited)</i>	<i>(unaudited)</i>		
Product revenue	\$ 14,803	\$ 13,085	\$ 48,914	\$ 39,029
License and other revenue	82	101	360	382
Total revenue	<u>14,885</u>	<u>13,186</u>	<u>49,274</u>	<u>39,411</u>
Cost of revenue	<u>6,243</u>	<u>4,688</u>	<u>19,700</u>	<u>15,317</u>
Gross profit	8,642	8,498	29,574	24,094
Operating expenses				
Sales and marketing	4,501	3,400	14,734	14,385
General and administrative	3,841	3,379	14,363	13,772
Research and development	12,358	10,180	49,458	37,472
Total operating expenses	<u>20,700</u>	<u>16,959</u>	<u>78,555</u>	<u>65,629</u>
Loss from operations	<u>(12,058)</u>	<u>(8,461)</u>	<u>(48,981)</u>	<u>(41,535)</u>
Other income (expense)				
Interest income	77	25	176	125
Interest expense	(474)	(273)	(1,536)	(880)
Other income (expense)	(168)	(59)	(160)	133
Total other income (expense)	<u>(565)</u>	<u>(307)</u>	<u>(1,520)</u>	<u>(622)</u>
Loss before provision for income taxes	<u>(12,623)</u>	<u>(8,768)</u>	<u>(50,501)</u>	<u>(42,157)</u>
Income tax expense (benefit)	55	14	100	40
Net loss	<u>\$ (12,678)</u>	<u>\$ (8,782)</u>	<u>\$ (50,601)</u>	<u>\$ (42,197)</u>
Net loss per share, basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.21)</u>	<u>\$ (1.15)</u>	<u>\$ (1.00)</u>
Weighted average number of shares outstanding basic and diluted	<u>46,458</u>	<u>42,429</u>	<u>44,100</u>	<u>42,157</u>
Other comprehensive loss				
Net loss	\$ (12,678)	\$ (8,782)	\$ (50,601)	\$ (42,197)
Foreign currency translation adjustments	86	44	77	36
Net unrealized losses on marketable securities, net of tax	(13)	(17)	(11)	3
Comprehensive loss	<u>\$ (12,605)</u>	<u>\$ (8,755)</u>	<u>\$ (50,535)</u>	<u>\$ (42,158)</u>

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

	Years ended December 31,		
	2016	2015	2014
Operating activities:			
Net loss	\$(50,601)	\$(42,197)	\$(38,263)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,916	3,405	2,656
Amortization of premiums on investments	89	180	702

Amortization of deferred debt issuance costs	388	285	—
Stock-based compensation	9,236	9,995	5,796
Provision for bad debt	13	25	—
Non-cash inventory adjustments	134	594	450
Gain on sale of investment in preferred stock	(9)	(223)	—
Other non-cash adjustments	145	186	185
Changes in operating assets and liabilities:			
Accounts receivable	(2,250)	(1,983)	(2,030)
Inventories	(3,450)	(1,286)	(229)
Prepaid expenses and other assets	(613)	(36)	(184)
Accounts payable	4,105	(757)	85
Accrued compensation	2,172	(458)	1,797
Other liabilities	1,088	355	(537)
Net cash used in operating activities	(35,637)	(31,915)	(29,572)
Investing activities			
Payments for intellectual property licenses	(1,500)	(550)	(350)
Purchases of property and equipment	(7,000)	(3,756)	(5,726)
Purchases of marketable securities	(33,688)	(22,646)	(28,054)
Proceeds from sales of marketable securities	8,015	223	7,497
Maturities of marketable securities	10,050	46,050	56,050
Net cash provided by (used in) investing activities	(24,123)	19,321	29,417
Financing activities			
Proceeds from issuance of common stock	30,920	884	812
Costs incurred in conjunction with public offering	(1,143)	—	—
Principal repayment of borrowings	(40)	(22)	(56)
Costs associated with debt issuance	(90)	(718)	—
Proceeds from borrowings	10,000	10,000	—
Proceeds from stock option exercises	712	989	531
Net cash provided by financing activities	40,359	11,133	1,287
Effect of exchange rate changes on cash	(25)	(9)	—
Net increase (decrease) in cash and cash equivalents	(19,426)	(1,470)	1,132
Cash and cash equivalents at beginning of year	35,385	36,855	35,723
Cash and cash equivalents at end of year	<u>\$ 15,959</u>	<u>\$ 35,385</u>	<u>\$ 36,855</u>
Non-cash investing and financing activities:			
Transfer of systems from property and equipment into inventory	\$ 263	\$ 225	\$ 256
Property and equipment costs incurred but not paid included in accounts payable	\$ 1,159	\$ 146	\$ 124
Intellectual property acquisition included in accrued expenses	\$ —	\$ 800	\$ 550
Supplemental cash flow information:			
Cash paid for interest	\$ 1,130	\$ 572	\$ 20
Cash received for interest	\$ 266	\$ 305	\$ 244
Cash paid for income taxes, net	\$ 65	\$ 10	\$ 24

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GenMark Diagnostics, Inc.
Hany Massarany
President/Chief Executive Officer
760-448-4325

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