

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 10, 2011

GENMARK DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34753
(Commission
File Number)

27-2053069
(I.R.S. Employer
Identification No.)

5964 La Place Court, Suite 100
Carlsbad, California
(Address of principal executive offices)

92008
(Zip Code)

760-448-4300
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

The information in this Item 2.02 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Item 2.02 shall not be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission.

On November 10, 2011, GenMark Diagnostics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2011 and related information. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits**(d) Exhibits**

99.1 Press release dated November 10, 2011.

* Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be incorporated by reference into any registration statement or other document filed with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

GENMARK DIAGNOSTICS, INC.

/s/ Paul Ross

Paul Ross

Chief Financial Officer

(principal financial and accounting officer)

Date: November 10, 2011

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 10, 2011.

GenMark Diagnostics Reports**Third Quarter 2011 Results****Revenues Grow 90% and Placements Increase by 22 to 141**

CARLSBAD, Calif., November 10, 2011 (BUSINESS WIRE) — **GenMark Diagnostics, Inc. (Nasdaq:GNMK)** today reported financial results for the third quarter ended September 30, 2011.

Revenues for the three months ended September 30, 2011 were \$1.3 million compared with \$684,000 during the third quarter of 2010. The 90% year-over-year increase in total revenue reflects an increase in the number of systems in the field, growth in the Company's test menu and a significant increase in the number of tests sold. Reagent revenues for the third quarter grew 83% year over year to \$1.2 million from \$656,000, while instrument and other revenues increased \$82,000 due mainly to higher partnering contract revenue. The Company placed net 22 analyzers during the quarter, bringing the installed base to 141.

The gross margin was a loss of \$469,000 for the three months ended September 30, 2011 compared with a loss of \$439,000 for the same period in 2010. The gross loss during the third quarter of 2011 was largely driven by a charge of \$421,000 against inventory, the impact of which was \$0.02 per share. The inventory charge reflects the write-off of several assay production lots that did not meet the Company's quality standards and other manufacturing inefficiencies arising from the Company's transfer of manufacturing operations from Pasadena to Carlsbad during the second quarter of 2011. The Company believes that these charges are non-recurring since the manufacturing issues were confined to and corrected during the quarter.

Operating expenses increased \$1.1 million to \$5.6 million during the third quarter of 2011. The increase in operating expenses was due primarily to higher consulting costs, increased headcount and additional spend on research and development. Research and development expenses were higher due to increased clinical trial costs and spending for new product development, specifically the Company's Hepatitis C Virus genotyping (HCVg) and Respiratory Viral Panel tests. The Company released its HCVg test for research use only during the third quarter of 2011.

Loss per share was \$0.31 for the third quarter of 2011, compared with a loss per share of \$0.42 in the third quarter of 2010. Excluding the inventory charges, loss per share would have been \$0.29 for the third quarter of 2011.

The Company ended the third quarter with \$36.0 million in cash and short-term investments compared with \$18.3 million at year-end. The Company raised net proceeds of approximately \$31.7 million through a follow-on equity offering in June 2011 and used \$14.0 million in cash flow from operations during the first nine months of 2011 compared with \$13.6 million in the first nine months of 2010. The Company intends to continue utilizing its cash balances for investing in new product development, infrastructure improvements and general corporate purposes.

“The third quarter of 2011 was another strong quarter for our company,” commented Hany Massarany, GenMark’s President and CEO. “During the quarter we expanded our test menu with the introduction of our Hepatitis C Virus genotyping RUO test, grew our installed base to 141 analyzers, and significantly increased revenue. Our focus continues to be new product development, commercial and operational execution,” Mr. Massarany further stated.

INVESTOR CONFERENCE CALL

GenMark will hold a conference call to discuss third quarter 2011 results and the outlook for the current year at 9:00AM EST today. The conference call and webcast can be accessed live through the Company’s website under the Investor Relations section and will be available for replay through November 25, 2011. To listen to the conference call, please dial (877) 312-5847 (US/Canada) or (253) 237-1154 (International) and use the conference ID number “23535246” approximately five minutes prior to the start time.

ABOUT GENMARK

GenMark Diagnostics 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. GenMark’s eSensor® XT-8 system supports a broad range of molecular diagnostic tests with a compact, easy-to-use workstation and self-contained, disposable test cartridges. GenMark tests that are FDA cleared for IVD use include the Cystic Fibrosis Genotyping Test, Warfarin Sensitivity Test, and Thrombophilia Risk Test. A Respiratory Viral Panel (RVP) is currently undergoing a clinical trial and tests for HCV Genotyping, 2C19, and KRAS are in development. 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 continued growth in sales of our diagnostic tests, the expansion of our diagnostic test menu, and the continued development of our technology, are all subject to risks and uncertainties that could cause our actual performance, operating results and financial position to differ materially. Some of these risks and uncertainties include, but are not limited to, risks related to our history of operating losses, our ability to successfully commercialize our products, the need for further financing and our ability to access the necessary additional capital for our business, inherent risk and uncertainty in the protection intellectual property rights, regulatory uncertainties regarding approval or clearance for our products, 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.

SOURCE: GenMark Diagnostics, Inc.

GenMark Diagnostics, Inc.

Paul Ross

Chief Financial Officer

760-448-4318

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except par value)

	As of September 30, 2011 <u>(Unaudited)</u>	As of December 31, 2010 (A) <u>(Audited)</u>
Current assets		
Cash and cash equivalents	\$ 31,001	\$ 18,329
Short-term investments	5,000	—
Accounts receivable, net of allowance of \$111 and \$39 at September 30, 2011 and December 31, 2010, respectively	724	678
Inventories	1,963	897
Other current assets	<u>428</u>	<u>2,193</u>
Total current assets	39,116	22,097
Property and equipment, net	3,122	2,702
Intangible assets, net	1,382	1,460
Other long-term assets	<u>80</u>	<u>55</u>
Total assets	<u>\$ 43,700</u>	<u>\$ 26,314</u>
Current liabilities		
Accounts payable	\$ 1,496	\$ 823
Accrued compensation	1,219	1,172
Current portion of loan payable	1,000	—
Other current liabilities	<u>2,705</u>	<u>1,945</u>
Total current liabilities	6,420	3,940
Long-term liabilities		
Loan payable	833	—
Other non-current liabilities	<u>630</u>	<u>1,307</u>
Total liabilities	<u>\$ 7,883</u>	<u>\$ 5,247</u>
Stockholders' equity		
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—
Common stock, \$0.0001 par value; 100,000 authorized; 20,478 and 11,728 issued and outstanding as of September 30, 2011 and December 31, 2010, respectively	2	1
Additional paid-in capital	199,300	166,009
Accumulated deficit	(163,027)	(144,493)
Accumulated other comprehensive loss	(458)	(450)
Total stockholders' equity	<u>35,817</u>	<u>21,067</u>
Total liabilities and stockholders' equity	<u>\$ 43,700</u>	<u>\$ 26,314</u>

(A) Includes adjustment to 12/31/10 balance sheet-see accompanying tables and footnote 1

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine months Ended September 30,	
	2011	2010 (B)	2011	2010 (B)
Product Revenue	\$ 1,206	\$ 656	\$ 2,765	\$ 1,563
License and other revenue	110	28	210	196
Total revenue	1,316	684	2,975	1,759
Cost of sales	1,785	1,123	4,580	2,372
Gross loss	(469)	(439)	(1,605)	(613)
Operating expenses				
Sales and marketing	1,328	1,173	3,767	3,567
General and administrative	2,405	1,603	6,338	5,798
Research and development	1,903	1,709	6,759	4,935
Total operating expenses	5,636	4,485	16,864	14,300
Loss from operations	(6,105)	(4,924)	(18,469)	(14,913)
Other income				
Other income (expense)	(180)	—	(50)	(1)
Interest income (expense)	(29)	7	6	16
Total other income (expense)	(209)	7	(44)	15
Loss before income taxes	(6,314)	(4,917)	(18,513)	(14,898)
Provision for income taxes	1	—	(21)	(5)
Net loss	<u>\$ (6,313)</u>	<u>\$ (4,917)</u>	<u>\$ (18,534)</u>	<u>\$ (14,903)</u>
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.42)	\$ (1.20)	\$ (1.63)
Weighted average number of shares outstanding	20,043	11,724	15,393	9,142
Condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2011 and 2010				
Net loss	\$ (6,313)	\$ (4,917)	\$ (18,534)	\$ (14,903)
Foreign currency translation adjustment	56	—	(8)	(35)
Comprehensive loss	<u>\$ (6,257)</u>	<u>\$ (4,917)</u>	<u>\$ (18,542)</u>	<u>\$ (14,938)</u>

(B) Includes reclassifications between certain cost pools-see accompanying tables and footnote 2

GENMARK DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine months Ended	
	September 30,	
	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:		
Net loss	\$(18,534)	\$(14,903)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	948	725
Share-based compensation	1,639	1,119
Inventory write-down	428	984
Changes in operating assets and liabilities:		
Trade accounts receivable	(46)	(363)
Inventories	(1,448)	(1,510)
Other current assets	1,741	183
Accounts payable	510	(446)
Accrued compensation	22	517
Accrued and other liabilities	731	104
Net cash used in operating activities	<u>(14,009)</u>	<u>(13,590)</u>
Investing activities:		
Payments for intellectual property licenses	(728)	—
Purchases of property and equipment	(1,172)	(1,398)
Purchase of short-term investments	(5,000)	—
Net cash used in investing activities	<u>(6,900)</u>	<u>(1,398)</u>
Financing activities:		
Proceeds from issuance of ordinary shares and common stock	34,532	27,600
Costs incurred in conjunction with public offering	(2,790)	(4,909)
Proceeds from borrowings	2,000	—
Principal repayment of borrowings	(167)	—
Proceeds from stock option exercises	—	5
Net cash provided by financing activities	<u>33,575</u>	<u>22,696</u>
Effect of foreign exchange rate changes	<u>6</u>	<u>(47)</u>
Net increase in cash and cash equivalents	12,672	7,661
Cash and cash equivalents at beginning of period	<u>18,329</u>	<u>16,483</u>
Cash and cash equivalents at end of period	<u>\$ 31,001</u>	<u>\$ 24,144</u>

TABLES AND FOOTNOTES
GENMARK DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS-See Footnote 1

(In thousands, except par value)
(Unaudited)

	As Reported December 31, 2010	(1) Adjustment	As Corrected December 31, 2010
Current assets			
Cash and cash equivalents	\$ 18,329	—	\$ 18,329
Accounts receivable, net of allowance of \$39	678	—	678
Inventories, net	897	—	897
Other current assets	2,193	—	2,193
Total current assets	22,097	—	22,097
Property and equipment, net	2,702	—	2,702
Intangible assets, net	71	1,389	1,460
Other long-term assets	55	—	55
Total assets	<u>\$ 24,925</u>	<u>\$ 1,389</u>	<u>\$ 26,314</u>
Current liabilities			
Accounts payable	\$ 823	—	\$ 823
Accrued compensation	1,172	—	1,172
Other current liabilities	1,250	695	1,945
Total current liabilities	3,245	695	3,940
Long-term liabilities			
Loan payable	—	—	—
Other non-current liabilities	613	694	1,307
Total liabilities	<u>\$ 3,858</u>	<u>\$ 1,389</u>	<u>\$ 5,247</u>
Stockholders' equity			
Common stock, \$0.0001 par value; 100,000 authorized; 11,728 issued and outstanding as of December 31, 2010	1	—	1
Preferred stock, \$0.0001 par value; 5,000 authorized, none issued	—	—	—
Additional paid-in capital	166,009	—	166,009
Accumulated deficit	(144,493)	—	(144,493)
Accumulated other comprehensive loss	(450)	—	(450)
Total stockholders' equity	21,067	—	21,067
Total liabilities and stockholders' equity	<u>\$ 24,925</u>	<u>\$ 1,389</u>	<u>\$ 26,314</u>

GENMARK DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS-SEE FOOTNOTE 2
(In thousands, except per share data)
(Unaudited)

	<u>As Reported</u> <u>Three Months Ended</u> <u>September 30,</u> <u>2010</u>	<u>Adjustments (2)</u> <u>Three Months Ended</u> <u>September 30,</u> <u>2010</u>	<u>As Corrected</u> <u>Three Months Ended</u> <u>September 30,</u> <u>2010</u>
Product Revenue	\$ 653	\$ 3	\$ 656
License and other revenue	14	14	28
Total revenue	667	17	684
Cost of sales	1,221	(98)	1,123
Gross loss	(554)	(115)	(439)
Operating expenses			
Sales and marketing	1,109	64	1,173
General and administrative	1,592	11	1,603
Research and development	1,669	40	1,709
Total operating expenses	4,370	115	4,485
Loss from operations	(4,924)	—	(4,924)
Other income			
Other income (expense)	—	—	—
Interest income (expense)	7	—	7
Total other income	7	—	7
Loss before income taxes	(4,917)	—	(4,917)
Provision for income taxes	—	—	—
Net loss	\$ (4,917)	\$ —	\$ (4,917)
Net loss per share, basic and diluted	\$ (0.42)	—	\$ (0.42)
Weighted average number of shares outstanding	11,724	—	11,724
Condensed consolidated statements of comprehensive loss for the three months ended September 30, 2010			
Net loss	\$ (4,917)	—	\$ (4,917)
Foreign currency translation adjustment	—	—	—
Comprehensive loss	\$ (4,917)	—	\$ (4,917)

GENMARK DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS SEE FOOTNOTE 2
(In thousands, except per share data)
(Unaudited)

	<u>As Reported</u> Nine months ended September 30, 2010	<u>Adjustments (2)</u> Nine months ended September 30, 2010	<u>As Corrected</u> Nine months ended September 30, 2010
Product Revenue	\$ 1,575	\$ (12)	\$ 1,563
License and other revenue	142	54	196
Total revenue	1,717	42	1,759
Cost of sales	2,651	(279)	2,372
Gross loss	(934)	(321)	(613)
Operating expenses			
Sales and marketing	3,371	196	3,567
General and administrative	5,761	37	5,798
Research and development	4,847	88	4,935
Total operating expenses	13,979	321	14,300
Loss from operations	(14,913)	—	(14,913)
Other income			
Other income (expense)	(1)	—	(1)
Interest income (expense)	16	—	16
Total other income	15	—	15
Loss before income taxes	(14,898)	—	(14,898)
Provision for income taxes	(5)	—	(5)
Net loss	\$ (14,903)	\$ —	\$ (14,903)
Net loss per share, basic and diluted	\$ (1.63)	\$ —	\$ (1.63)
Weighted average number of shares outstanding	9,142	—	9,142
Condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2010			
Net loss	\$ (14,903)	\$ —	\$ (14,903)
Foreign currency translation adjustment	(35)	—	(35)
Comprehensive loss	\$ (14,938)	\$ —	\$ (14,938)

- (1) Subsequent to the issuance of the 2010 audited financial statements, the Company concluded that a contract for the purchase of certain intellectual property rights should have been recorded as both an asset and a liability in the financial statements for the periods ended December 31, 2010 and March 31, 2011. The Company has recorded this contract which results in an increase of intangible assets and corresponding increases in current and long-term liabilities of \$1,389,000 for the year ended December 31, 2010.
- (2) Subsequent to the issuance of the 2010 audited financial statements, the Company further concluded that certain expenses were classified incorrectly in its Consolidated Statements of Operations for the periods presented herein, with no net impact to operating income, net income, statements of cash flows or balance sheets. The Company has corrected these immaterial misstatements. These corrections result in reductions to cost of goods sold of \$98,000 and \$279,000 in the quarter and nine-month period ended September 30, 2010, respectively, and corresponding increases to revenues, sales and marketing and research and development expenses.