
**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): February 6, 2013

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

Registrant's telephone number, including area code: 610-882-1820

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:

- 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))
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Item 2.02 – Results of Operations and Financial Condition.

On February 6, 2013, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2012, and providing financial guidance for the first quarter of 2013. A copy of the press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

Item 7.01 – Regulation FD Disclosure.

On February 6, 2013, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company’s President and Chief Executive Officer, and Ronald H. Spair, the Company’s Chief Financial Officer and Chief Operating Officer, discussed the Company’s consolidated financial results for the quarter and full year ended December 31, 2012, provided financial guidance for the first quarter of 2013 and described certain business developments. A copy of the prepared remarks of Messrs. Michels and Spair is attached as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

The information in this Item and attached Exhibit shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall such information and Exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such a filing. The fact that the information and Exhibit are being furnished should not be deemed an admission as to the materiality of any information contained therein. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report or attached Exhibit.

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated February 6, 2013, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2012, and providing financial guidance for the first quarter of 2013.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2012 Analyst/Investor Conference Call Held February 6, 2013.

Signatures

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

ORASURE TECHNOLOGIES, INC.

Date: February 6, 2013

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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Chief Financial Officer
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www.orasure.com

OraSure Announces Full-Year and Fourth Quarter 2012 Financial Results

BETHLEHEM, PA – February 6, 2013 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the full-year and fourth quarter of 2012.

Quarterly Highlights

- Consolidated net revenues were \$87.8 million for the full-year 2012, a 7% increase from the comparable period of 2011. Net revenues for the current period included \$14.3 million from the Company's molecular collection systems subsidiary, DNA Genotek Inc. ("DNAG"), acquired in August 2011. DNAG net revenues from the August 17, 2011 acquisition date through December 31, 2011 were \$6.2 million.
- Consolidated net revenues were \$22.1 million for the fourth quarter of 2012, a 7% decrease from the comparable quarter of 2011. This decrease was primarily the result of lower sales of the Company's substance abuse testing and cryosurgical systems products.
- Consolidated net loss for the year ended December 31, 2012 was \$15.1 million, or \$0.29 per share, which compares to a net loss of \$8.8 million, or \$0.19 per share, for 2011. The full-year net loss for 2012 included \$9.9 million in costs associated with the commercialization of the Company's OraQuick® In-Home HIV test.

- Consolidated net loss for the fourth quarter of 2012 was \$5.9 million, or \$0.11 per share, which compares to net income of \$115,000, or \$0.00 per share, for the fourth quarter of 2011. The fourth quarter 2012 net loss included \$5.2 million in costs associated with the OraQuick® In-Home HIV test commercialization.
- Included in the 2012 full-year and fourth quarter revenues were gross sales of the OraQuick® In-Home test of \$902,000, which were reduced by trade spend, cash discounts and an estimate for returns and allowances resulting in net revenues of \$546,000 recorded for each period. Revenue for this product is recognized upon the consummation of a sale to a retail customer either in a store or over the internet.
- Cash totaled \$87.9 million at December 31, 2012 compared to \$23.9 million at December 31, 2011.

“The highlight of 2012 was the receipt of FDA approval of our OraQuick® In-Home test,” said Douglas A. Michels, President and CEO of OraSure Technologies. “We now have the first and only rapid HIV test available for use by consumers. During the fourth quarter, we launched our national public relations and advertising campaign and began selling this product to retailers across the country. Apart from the commercial opportunity for our Company, we believe the OraQuick® In-Home HIV test will significantly benefit public health by offering individuals who might not otherwise get tested a simple and confidential way to learn their HIV status in the comfort of their own homes.”

Financial Results

Net product revenues for the year ended December 31, 2012 increased 6% primarily as a result of a full year of molecular collection system sales and higher cryosurgical systems sales. These increases were partially offset by lower sales of the Company’s infectious disease testing, substance abuse testing and insurance risk assessment products. Product revenues for the quarter ended December 31, 2012 decreased 7% primarily as a result of lower sales of the Company’s substance abuse testing and cryosurgical systems products. These decreases were partially offset by higher sales of infectious disease testing and molecular collection systems products.

Licensing and product development revenues for the year ended December 31, 2012 increased to \$2.1 million from \$1.2 million for the full-year of 2011. This increase was primarily attributed to a \$1.0 million milestone payment received under the Company’s HCV collaboration agreement with Merck, partially offset by lower royalties under a license related to the Company’s cryosurgical patents. The HCV collaboration with Merck has since been terminated. Licensing and product development revenues for the fourth quarter of 2012 and 2011 were \$198,000 and \$191,000, respectively, reflecting royalties related to the Company’s cryosurgical patents.

Consolidated gross margin for each of the years ended December 31, 2012 and 2011 was 63%. Consolidated gross margin for the three months ended December 31, 2012 was 60% compared to 62% for the three months ended December 31, 2011. The current quarter gross margin was negatively impacted by a change in product mix and a decline in the absorption of labor and overhead costs.

For the year ended December 31, 2012, consolidated operating expenses were \$71.8 million, an increase over the \$61.1 million reported for the year ended December 31, 2011. This increase resulted from the inclusion of a full-year of DNAG operating expenses and \$9.9 million of costs related to the OraQuick® In-Home HIV Test commercialization. These increases were partially offset by lower clinical trial costs related to the Company's OraQuick® In-Home HIV test.

Consolidated operating expenses increased to \$19.4 million for the fourth quarter of 2012, from \$14.9 million in the comparable period of 2011. This increase was the result of higher costs related to the commercialization of the Company's OraQuick® In-Home HIV test. The current quarter expenses included \$5.2 million of promotional and advertising costs related to this product.

For the year and three months ended December 31, 2012, the Company recorded an income tax benefit of \$1.4 million and \$259,000, respectively, associated with the DNAG loss before income taxes and certain Canadian research and development and investment tax credits. The income tax benefit recorded for the full year of 2012 was negatively impacted by a second quarter adjustment to the Company's Canadian deferred tax liability to reflect a change in the enacted Canadian provincial income tax rates.

Cash totaled \$87.9 million at December 31, 2012 compared to \$23.9 million at December 31, 2011. Working capital was \$103.5 million at December 31, 2012 compared to \$30.9 million at December 31, 2011. In July 2012, the Company completed a secondary offering of 6.1 million shares of its common stock, resulting in net proceeds of \$70.2 million after expenses of the offering.

First Quarter 2013 Outlook

The Company expects total consolidated net revenues to range from \$20.0 to \$21.0 million and is projecting a consolidated net loss of approximately \$0.18 - \$0.19 per share for the first quarter of 2013.

Revenues projected for the first quarter of 2013 are expected to be sequentially down from the fourth quarter of 2012 primarily as a result of lower infectious disease testing sales to the professional market. During the past several years, the first quarter of each year has historically been the lowest revenue quarter of the year for this part of the Company's base business, while the fourth quarter has been the highest.

The projected net loss for the first quarter includes the impact of the medical device tax imposed under the Affordable Care Act and higher patent royalties payable on the Company's OraQuick® professional products under a litigation settlement previously reached with Alere (formerly Inverness Medical) in 2009. In addition, this projection includes approximately \$7.3 million in advertising and promotional costs related to the Company's OraQuick® In-Home HIV test.

Financial Data
**Condensed Consolidated Financial Data
(In thousands, except per-share data)**

	Unaudited			
	Three months ended December 31,		Year ended December 31,	
	2012	2011	2012	2011
Results of Operations				
Net revenues	\$22,144	\$23,690	\$ 87,820	\$81,881
Cost of products sold	8,893	9,094	32,249	30,164
Gross profit	<u>13,251</u>	<u>14,596</u>	<u>55,571</u>	<u>51,717</u>
Operating expenses:				
Research and development	2,893	3,297	12,445	18,407
Sales and marketing	11,597	6,357	37,087	22,383
General and administrative	4,911	5,222	22,309	20,325
Total operating expenses	<u>19,401</u>	<u>14,876</u>	<u>71,841</u>	<u>61,115</u>
Operating loss	(6,150)	(280)	(16,270)	(9,398)
Other income (expense)	25	(158)	(242)	(312)
Loss before income taxes	(6,125)	(438)	(16,512)	(9,710)
Income tax benefit	(259)	(553)	(1,397)	(869)
Net income (loss)	<u>\$ (5,866)</u>	<u>\$ 115</u>	<u>\$ (15,115)</u>	<u>\$ (8,841)</u>
Earnings (loss) per share:				
Basic and Diluted	<u>\$ (0.11)</u>	<u>\$ —</u>	<u>\$ (0.29)</u>	<u>\$ (0.19)</u>
Weighted average shares:				
Basic	<u>55,224</u>	<u>47,264</u>	<u>51,457</u>	<u>46,908</u>
Diluted	<u>55,224</u>	<u>48,893</u>	<u>51,457</u>	<u>46,908</u>

Summary of Revenues by Market and Product (Unaudited)

<u>Market</u>	<u>Three Months Ended December 31,</u>				
	<u>Dollars</u>		<u>% Change</u>	<u>Percentage of Net Revenues</u>	
	<u>2012</u>	<u>2011</u>		<u>2012</u>	<u>2011</u>
Infectious disease testing	\$ 11,846	\$ 11,592	2%	54%	49%
Substance abuse testing	2,101	3,487	(40)	9	15
Cryosurgical systems	2,696	3,139	(14)	12	13
Molecular collection systems	4,266	4,194	2	19	17
Insurance risk assessment	1,037	1,087	(5)	5	5
Net product revenues	21,946	23,499	(7)	99	99
Licensing and product development	198	191	4	1	1
Net revenues	<u>\$22,144</u>	<u>\$23,690</u>	(7)%	<u>100%</u>	<u>100%</u>

<u>Market</u>	<u>Year Ended December 31,</u>				
	<u>Dollars</u>		<u>% Change</u>	<u>Percentage of Net Revenues</u>	
	<u>2012</u>	<u>2011</u>		<u>2012</u>	<u>2011</u>
Infectious disease testing	\$42,728	\$44,691	(4)%	49%	55%
Substance abuse testing	9,407	12,498	(25)	11	15
Cryosurgical systems	14,876	12,046	23	17	15
Molecular collection systems	14,258	6,216	129	16	8
Insurance risk assessment	4,484	5,232	(14)	5	6
Net product revenues	85,753	80,683	6	98	99
Licensing and product development	2,067	1,198	73	2	1
Net revenues	<u>\$87,820</u>	<u>\$81,881</u>	7%	<u>100%</u>	<u>100%</u>

<u>OraQuick® Revenues</u>	<u>Three Months Ended December 31,</u>			<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>% Change</u>	<u>2012</u>	<u>2011</u>	<u>% Change</u>
Domestic HIV	\$ 9,157	\$ 9,775	(6)%	\$34,265	\$38,722	(12)%
International HIV	773	721	7	3,061	3,011	2
Domestic HIV OTC	546	—	N/A	546	—	N/A
Domestic HCV	847	426	99	2,805	890	215
International HCV	326	387	(16)	1,059	672	58
Net OraQuick® revenues	<u>\$11,649</u>	<u>\$11,309</u>	3%	<u>\$41,736</u>	<u>\$43,295</u>	(4)%

<u>Intercept® Revenues</u>	<u>Three Months Ended December 31,</u>			<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>% Change</u>	<u>2012</u>	<u>2011</u>	<u>% Change</u>
Domestic	\$1,354	\$2,096	(35)%	\$6,335	\$8,004	(21)%
International	90	439	(79)	706	1,912	(63)
Net Intercept® revenues	<u>\$1,444</u>	<u>\$2,535</u>	(43)%	<u>\$7,041</u>	<u>\$9,916</u>	(29)%

<u>Cryosurgical Systems Revenues</u>	<u>Three Months Ended December 31,</u>			<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>% Change</u>	<u>2012</u>	<u>2011</u>	<u>% Change</u>
Professional domestic	\$1,818	\$1,678	8%	\$ 7,159	\$ 6,775	6%
Professional international	352	412	(15)	1,462	1,400	4
Over-the-Counter	526	1,049	(50)	6,255	3,871	62
Net cryosurgical systems revenues	<u>\$2,696</u>	<u>\$3,139</u>	(14)%	<u>\$14,876</u>	<u>\$12,046</u>	23%

Condensed Consolidated Balance Sheets

(Unaudited)	December 31, 2012	December 31, 2011
<u>Assets</u>		
Cash	\$ 87,888	\$ 23,878
Accounts receivable, net	17,545	17,159
Inventories	12,758	9,621
Other current assets	2,212	2,178
Property and equipment, net	18,546	19,855
Intangible assets, net	27,207	30,383
Goodwill	25,445	24,740
Other non-current assets	124	47
Total assets	<u>\$ 191,725</u>	<u>\$ 127,861</u>
<u>Liabilities and Stockholders' Equity</u>		
Current portion of long-term debt	\$ —	\$ 7,292
Accounts payable	3,380	4,142
Deferred revenue	5,580	1,318
Accrued expenses	7,960	9,224
Other non-current liabilities	89	—
Deferred income taxes	4,401	5,636
Stockholders' equity	170,315	100,249
Total liabilities and stockholders' equity	<u>\$ 191,725</u>	<u>\$ 127,861</u>

Additional Financial Data (Unaudited)	Year ended December 31,	
	2012	2011
Capital expenditures	\$ 2,019	\$ 2,505
Net proceeds from public offering	\$70,245	\$ —
Acquisition of DNA Genotek, Inc., net of cash acquired	\$ —	\$49,730
Depreciation and amortization	\$ 7,250	\$ 4,891
Stock based compensation	\$ 5,197	\$ 4,100
Cash used in operating activities	\$ 5,372	\$ 2,994

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2012 fourth quarter and full year financial results, business developments and financial guidance for the first quarter of 2013, beginning today at 5:00 p.m. Eastern Time (2:00 p.m. Pacific Time). On the call will be Douglas A. Michels, President and Chief Executive Officer, Ronald H. Spair, Chief Financial Officer and Chief Operating Officer, and Kathleen Weber, Senior Vice President and General Manager, Consumer Products. The call will include prepared remarks by management and a question and answer session.

In order to listen to the conference call, please either dial 877-348-9357 (Domestic) or 970-315-0488 (International) and reference Conference ID #87367276 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Info link. A replay of the call will be archived on OraSure Technologies' web site shortly after the call has ended and will be available for seven days. A replay of the call can also be accessed until February 13, 2013, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #87367276.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. In July 2012, the Company received approval from the U.S. Food and Drug Administration for the Company's OraQuick® In-Home HIV Test for sale directly to consumers in the over-the-counter (OTC) market – making it the first and only rapid OTC HIV test approved in the U.S. In addition, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; ability of DNA Genotek to achieve its

financial and strategic objectives; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products, including the OraQuick® In-Home HIV Test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2011, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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OraSure Technologies, Inc.
2012 Fourth Quarter and Full Year
Analyst/Investor Conference Call
February 6, 2013

Prepared Remarks of Douglas A. Michels and Ronald H. Spair

Please see "Important Information" at the conclusion of the following prepared remarks.

Introduction – Doug Michels

Thanks Judy. Good afternoon everyone and welcome to our call.

We finished 2012 on a positive note. Both the Company's revenues and net loss for Q4 came in above our guidance and our consolidated full year revenues exceeded our 2011 revenues. We also had some notable developments in 2012.

As you know, last year we achieved the most significant milestone in our history when we received FDA approval of our OraQuick® In-Home HIV test, and we began selling this exciting new product to consumers. As I will discuss later in the call, the commercial launch of this product is going well, with weekly consumer purchases increasing in response to promotion. I would also like to mention that Kathy Weber, OraSure's Senior Vice President and General Manager, Consumer Products is here with Ron and me this afternoon. Kathy will be able to respond to any questions you may have about our OTC efforts during the Q&A session.

2012 was also the first full year of contribution from our molecular collection systems subsidiary, DNA Genotek. DNA Genotek performed well in both the commercial market and the challenging research and academic market. We are excited about the future of molecular diagnostics and DNA Genotek is well positioned for growth in 2013 and beyond.

So, with that as a brief intro, let me now turn the call over to Ron for his financial review.

Fourth Quarter 2012 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our fourth quarter 2012 consolidated revenues were \$22.1 million compared to \$23.7 million reported in 2011. Our consolidated product revenues decreased 7% as a result of the lower sales of our substance abuse, cryosurgical systems and insurance risk assessment products. These decreases were partially offset by higher sales of our infectious disease products and higher molecular collection systems sales.

Our infectious disease testing revenues were \$11.8 million in the fourth quarter of 2012 compared to \$11.6 million in the fourth quarter of 2011. The overall 2% increase was primarily a result of the inclusion of the first sales of our OraQuick® In-Home HIV test and higher OraQuick® HCV sales, partially offset by lower OraQuick® HIV professional sales.

During the fourth quarter of 2012, gross sales of our OraQuick® In-Home HIV test were \$902,000. Under applicable accounting rules, this amount was offset by trade spend, discounts and returns and allowances resulting in net revenues recorded of \$546,000.

Fourth quarter domestic HIV revenues were down \$618,000, or 6%, due to various factors, including changes in public health testing programs and their timing of purchases, reductions in government funding, price competition, and a shift to automated laboratory-based blood tests by some customers. International HIV revenues increased \$52,000 to \$773,000 in the fourth quarter of 2012.

Fourth quarter domestic HCV revenues increased \$421,000 or 99% largely as a result of broader adoption of our product by domestic customers who are able to use a CLIA waived product. International HCV revenues for the fourth quarter remained approximately the same when compared to the fourth quarter of 2011.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, increased slightly to \$4.3 million in the fourth quarter of 2012 compared to \$4.2 million in 2011. Revenues for the prior year quarter included a \$1.5 million purchase by DNA Genotek's largest customer which did not repeat in Q4 2012.

In substance abuse testing, revenues decreased to \$2.1 million in the fourth quarter of 2012 from \$3.5 million in the fourth quarter of 2011, primarily as a result of lower Intercept® sales and lower sales of our Q.E.D.® point-of-care saliva alcohol test. Fourth quarter 2011 Q.E.D.® revenues were unusually high due to our fulfillment of an order backlog resulting from production issues that were resolved in October 2011. The decrease in Intercept® sales was the result of lower purchases by our largest domestic laboratory distributor who began selling its own competitive oral fluid drug testing system at the end of 2011, and lower international sales due to a reduction in purchases by our UK laboratory distributor.

Fourth quarter 2012 cryosurgical revenues decreased 14% compared to the fourth quarter of 2011, primarily as a result of lower OTC sales and lower professional sales in the international marketplace, partially offset by an increase in professional sales in the domestic market.

OTC cryosurgical sales during the quarter decreased \$523,000, when compared to 2011, largely as a result of the timing of distributor purchases and the resolution of certain regulatory issues that increased sales in the prior year period.

Overall professional cryosurgical sales increased by 4% to \$2.2 million due to

distributor ordering patterns in both the domestic and international markets.

Gross Margin – Ron Spair

Turning to Gross Margin, our overall margin for Q4 of 2012 was 60% compared to 62% reported for the fourth quarter of 2011. The lower margin in 2012 was a result of an unfavorable change in product mix and a decline in the absorption of labor and overhead costs related somewhat to the impact of Hurricane Sandy.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the fourth quarter increased \$4.5 million, or 30%, compared to the fourth quarter of 2011. Research and development expenses decreased from \$3.3 million to \$2.9 million for the quarter due to lower clinical trial costs associated with our OraQuick® In-Home HIV test and lower international product registration costs. Sales and marketing expenses were \$11.6 million for the fourth quarter, an increase of \$5.2 million over 2011 due to the inclusion of \$5.2 million of costs related to the commercialization of our OraQuick® In-Home HIV test. General and administrative expenses decreased from \$5.2 million to \$4.9 million due to lower legal, accounting and consulting fees.

Net Loss – Ron Spair

From a bottom line perspective, we reported a net loss of \$5.9 million, or \$0.11 per share for the fourth quarter of 2012, compared to net income of \$115,000, or \$0.00 per share, for the same period of 2011.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance at December 31, 2012 was \$87.9 million compared to \$23.9 million at December 31, 2011. We completed a secondary stock offering in Q3 of 2012 which increased our cash balance by approximately \$70 million.

Cash used in operating activities in the fourth quarter of 2012 was \$1.4 million compared to \$1.1 million of cash generated from operating activities in the fourth quarter of 2011.

First Quarter 2013 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the first quarter of 2013, we are projecting consolidated revenues of approximately \$20.0 to \$21.0 million and a consolidated net loss per share of approximately \$0.18 to \$0.19 for the quarter.

Revenues projected for Q1 of 2013 are sequentially down from our performance in Q4 of 2012, primarily as a result of lower infectious disease product revenues partially offset by higher HIV-OTC sales. Q1 has historically been the softest quarter of the year for our base infectious disease business while Q4 has been the strongest. Additionally, we did see a somewhat higher than expected Q4 – 2012 buy in from our domestic professional cryosurgery distributors in advance of a price increase that took effect in early January 2013.

From a profitability perspective, the medical device excise tax and higher royalties under the terms of our settlement agreement reached with Alere in 2009 are included in the cost of goods sold for the affected products. We believe that our ongoing gross margins should be in the upper 50% range. We will also be investing \$7.3 million in Q1-2013 to support our direct to consumer advertising campaign for the OraQuick® In-Home HIV test.

With that, I will now turn the call back over to Doug.

Business Update – Doug Michels

Thanks, Ron.

HIV-OTC – Doug Michels

Much of our recent focus has been on commercializing our OraQuick® In-Home HIV test. We are pleased with the progress to date. Consumer purchases are responding to our national PR and advertising campaigns, with sales increasing on a weekly basis.

As you may recall, we initiated our national TV advertising in December and, as a result, weekly consumer sales during December grew 30% over the comparable levels in November. In January, we increased the frequency of our TV spots and consumer sales were up 40% over December. Consumers are now purchasing about 4,000 units per week compared to about 2,000 units per week in November of last year. We are seeing similar growth in internet sales through our website.

TV promotion is an effective tool to generate broad awareness among a large population, such as sexually active adults. It is clear from our results to date that our advertising is working. This week we are taking steps to make our TV promotion more efficient by introducing shorter duration ads (i.e. 15 to 30 seconds versus 45 seconds) into the mix. This allows us to increase the reach and frequency of our advertising at the same cost. We also continue to supplement our TV advertising with digital and print media, which are an efficient and effective way to communicate with our target customers.

In addition to national TV advertising, our promotional campaign will soon incorporate more locally based, on-the-ground tactical marketing. Examples include promotion at music festivals and Gay Pride events and the use of local radio ads and increased local signage and banners. Initially, these local activities will occur primarily in the 6-10 urban areas that have the largest populations of our target consumers. We will also

continue working with Magic Johnson to supplement our awareness efforts during 2013.

In evaluating our progress, one thing to keep in mind is the expected purchase cycle for our test. Based on market research, we believe there is generally a lag between when many consumers first become aware of the product and when they decide to purchase. In some cases this lag can be several months. This obviously impacts our sales growth rate and is a major reason why our advertising is focused on building broad consumer awareness. This also highlights the importance of continuing to keep the brand message in front of the consumer.

On the sales side, each of our major retailers such as CVS, Rite Aid, Wal-Mart and Walgreens, remain highly supportive and are pleased to see that sales are increasing in response to our promotional efforts. With respect to internet activity, as of mid-January we had almost 500,000 unique visitors to our OraQuick.com website. We estimate that about 50% of this traffic comes through mobile devices such as smart phones and tablets. We believe this reflects the effectiveness of our ad campaign and in particular the use of various types of digital media. In the near future, we expect to launch an app for mobile devices which will allow consumers to find a local retailer carrying our product, watch a product demonstration video or visit our website to make a purchase.

A final area I want to address is our consumer support center, which is functioning well and is exceeding our performance goals. Approximately, 85% of calls are received, between the hours of 7 a.m. and 10 p.m., and the average response time is 5.8 seconds. The types of calls have shifted from asking about price and product availability to usage of the test and interpreting results. Importantly, we have received a minimal number of product complaints. This suggests that consumers are able to use the product properly. Additionally, consumers testing positive with our product are using the medical provider referral services offered by our call center.

So, in summary, our efforts to commercialize the OraQuick® In-Home HIV test are progressing well. Our awareness and consumer activation efforts through TV and other promotional activities are proving effective as they stimulate sales growth. We expect this trend to continue as we execute against our strategies throughout 2013.

OraQuick® HCV – Doug Michels

With respect to our OraQuick® HCV test, we are encouraged by the substantial growth experienced during 2012. Revenues for this product were up 44% for the year compared to 2011. However, we still have higher expectations for this product, and our sales and marketing group will continue to focus on market development, especially in the public health, hospital and physician office markets.

During the fourth quarter, we were pleased to see that several major organizations, including the American Association for the Study of Liver Disease, the Infectious Disease Society of America and the National Viral Hepatitis Roundtable, announced their support for the CDC's new guidelines recommending that all baby boomers receive a one-time test for HCV. In addition, the U.S. Preventive Services Task Force ("USPSTF") issued new draft recommendations for HCV testing during the quarter. In these draft recommendations, the USPSTF gave a "B" grade to HCV testing for persons who inject drugs or are otherwise identified with risks for infection. This is significant in that at-risk HCV testing previously had a "C" grade. A "B" grade or better is generally needed from the USPSTF before physicians will offer the service consistently. So this change should result in greater HCV testing, particularly among individuals at risk for the disease.

Other Products – Doug Michels

Moving from our newer products, I want to briefly comment on our professional

HIV and our substance abuse testing products.

As noted in prior calls, our professional OraQuick® HIV business has been impacted by reduced government funding and increasing competition. This is likely to continue. The availability of government funding is particularly important in the public health market, and may come under greater pressure if the mandatory cost reductions occur under Federal sequestration.

In substance abuse, as discussed on prior calls, we have experienced delays in our development efforts for high throughput assays primarily because Roche has been unable to obtain FDA clearance of an assay for THC, or marijuana. We are in discussions with Roche about this assay and the future of our collaboration.

DNA Genotek Acquisition – Doug Michels

Finally, turning briefly to our molecular collection systems business — DNA Genotek had a strong fourth quarter and year in 2012. New orders were higher than 2011, and the company continued to deliver product to large commercial customers whose test offerings are seeing increased adoption in the genetic testing market. In addition, the academic research market, which has long been a core area for DNA Genotek, has continued to deliver solid revenues despite a less than optimal funding environment. DNA Genotek had a particularly strong quarter in the European research market during Q4.

We remain enthusiastic and confident in the growth prospects for DNA Genotek. The company's largest customer recently confirmed that it will make a substantial purchase during 2013 and another long-standing customer in the United Kingdom recently signed a multi-year supply agreement. These activities, when combined with the increase in new customer orders during 2012 and some new products under development, have set the stage for what we believe will be a strong 2013 from DNA Genotek.

Conclusion

So in conclusion, now that 2012 is completed our focus for the New Year is on execution. We will continue to devote significant time and resources to making our OraQuick® In-Home HIV test a commercial success. We will also focus on expanding sales of our OraQuick® HCV product and improving the performance of our professional HIV and substance abuse businesses. We look forward to discussing our results on future calls.

And with that, I will now open the floor to your questions. Operator please proceed.

* * * *

[Q&A session]

Conclusion – Doug Michels

Thank you for participating on today's call and for your continued interest in OraSure. Have a good afternoon and evening.

Important Information

This document contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable

specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors and success of direct sales efforts; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; the ability of DNA Genotek to achieve its financial and strategic objectives; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products, including the OraQuick® In-Home HIV Test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical product components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products

internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2011, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.