
**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 5, 2014

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))
-

Item 2.02 – Results of Operations and Financial Condition.

On February 5, 2014, OraSure Technologies, Inc. (“OraSure” or the “Company”) issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2013, and providing financial guidance for the first quarter of 2014. 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 5.02 – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Dr. Stephen Lee, OraSure’s Executive Vice President, Research and Development and Chief Science Officer, will be retiring from the Company effective February 28, 2014. Dr. Lee’s responsibilities will be assumed by Dr. Eric Whitters, who currently serves as OraSure’s Director, Research and Development. Effective March 1, 2014, Dr. Whitters will be promoted to Senior Vice President, R&D, Regulatory, Quality and Clinical Affairs for the Company. Dr. Whitters will also become a member of the Company’s internal senior management team, known as the Executive Committee, and will report directly to the Company’s President and Chief Executive Officer, Douglas A. Michels. Dr. Whitters joined the Company in November 2012, and has over 20 years of experience in the diagnostics industry. Prior to joining OraSure, Dr. Whitters served as Vice President, Research and Development and as Vice President, Research of Novartis Diagnostics where he had responsibility for development of molecular diagnostic products, among other matters. Prior to serving at Novartis Diagnostics, Dr. Whitters held various research and development positions of increasing seniority at Siemens Healthcare Diagnostics.

Item 7.01 – Regulation FD Disclosure.

On February 5, 2014, the Company held a webcast conference call with analysts and investors, during which Mr. Michels 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, 2013, provided financial guidance for the first quarter of 2014 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 5, 2014, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2013, and providing financial guidance for the first quarter of 2014.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2013 Analyst/Investor Conference Call Held February 5, 2014.

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.

Date: February 5, 2014

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett
Jack E. Jerrett
Senior Vice President, General Counsel
and Secretary

Index to Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated February 5, 2014, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2013, and providing financial guidance for the first quarter of 2014.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2013 Analyst/Investor Conference Call Held February 5, 2014.



OraSure Technologies, Inc.

Company Contact:

Ronald H. Spair
Chief Financial Officer
610-882-1820
Investorinfo@orasure.com
www.orasure.com

OraSure Announces Record Full-Year and Quarterly Revenues

BETHLEHEM, PA – February 5, 2014 – (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 2013.

Financial Highlights

- The Company reported record revenues for both the fourth quarter and full-year 2013. Consolidated net revenues for the fourth quarter were \$28.8 million, a 30% increase from the comparable quarter of 2012. Consolidated net revenues for the full-year were \$98.9 million, a 13% increase from the comparable period of 2012. During the fourth quarter and full-year period, net product revenues increased 31% and 15%, respectively, compared to the year ago periods. These increases were primarily due to sales of the Company's OraQuick® In-Home HIV test (which included a non-recurring revenue adjustment described below) and higher revenues from the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG").
- Gross sales of the Company's OraQuick In-Home HIV test were \$4.3 million and \$9.9 million for the fourth quarter and full-year 2013, respectively. These gross sales included a non-recurring favorable \$2.7 million adjustment made in December 2013 to account for a change in the Company's revenue recognition policy related to this product. The gross sales for the fourth quarter and full-year of 2013 were reduced by customer allowances for cooperative advertising, cash discounts and other allowances, resulting in net revenues of \$3.9 million and \$9.1 million recorded in each respective period. Gross and net sales of the Company's OraQuick® In-Home test for the fourth quarter and full-year 2012 were \$902,000 and \$546,000, respectively.

- Net revenues generated by DNAG during the fourth quarter of 2013 were \$6.8 million, a 60% increase from the comparable period in 2012. DNAG net revenues for the full-year 2013 were \$20.4 million, a 43% increase from 2012. The increases in both periods were primarily the result of higher sales to commercial customers.
- Net revenues for the Company's OraQuick® rapid HCV test reached \$1.9 million for the fourth quarter and \$5.1 million for the full-year 2013, representing increases of 65% and 32%, respectively, from the comparable 2012 periods. This growth reflects increasing demand for the product in both the domestic and international markets.
- Consolidated net income for the fourth quarter of 2013 was \$6.2 million, or \$0.11 per share, which compares to a net loss of \$5.9 million, or \$0.11 per share, for the fourth quarter of 2012. Consolidated net loss for the full-year 2013 was \$11.2 million, or \$0.20 per share, which compares to a net loss of \$15.1 million, or \$0.29 per share, for 2012. The results for the fourth quarter and full-year 2013 included \$4.6 million and \$18.8 million in advertising and promotional expenses, respectively, associated with the Company's OraQuick® In-Home HIV test. Also included in the results for both periods was an \$8.3 million settlement payment received by the Company for the termination of the Company's oral fluid assay collaboration agreement with Roche Diagnostics.

"We are pleased with the Company's overall financial results and especially the solid revenue growth delivered in 2013," said Douglas A. Michels, President and CEO of OraSure Technologies. "Our molecular collection systems business was particularly strong, growing by more than 40% for the year. Infectious disease revenues also increased largely due to contributions from our newest products, the OraQuick® In-Home HIV test and the OraQuick® rapid HCV test. The transition to a new collaboration for the supply of high throughput homogeneous drug assays represents another highlight from the year that should enable growth in our substance abuse testing business."

Financial Results

Consolidated net product revenues for the fourth quarter and full-year of 2013 increased 31% and 15%, respectively, from the comparable periods of 2012. The fourth quarter increase was primarily a result of higher sales of the Company's infectious disease testing products, which included the non-recurring net favorable \$2.5 million accounting adjustment, and higher molecular collection systems and cryosurgical systems product sales, partially offset by lower sales of the Company's insurance risk assessment products. The increase in net product

revenues for the full-year of 2013 was primarily the result of higher sales of the Company's infectious disease testing products, including the \$2.5 million net accounting adjustment, and higher sales of molecular collections systems products, partially offset by lower sales of the Company's substance abuse testing, cryosurgical systems and insurance risk assessment products.

The Company had no consolidated licensing and product development revenues for the fourth quarter of 2013 as a result of the expiration of certain patents licensed to a third party. This compares to \$198,000 recorded for the fourth quarter of 2012. Consolidated licensing and product development revenues for the year ended December 31, 2013 decreased to \$623,000 from \$2.1 million in the comparable period of the prior year, primarily due to the absence of a \$1.0 million milestone payment received in the first quarter of 2012 under the Company's HCV collaboration agreement with Merck. No similar payment was received during 2013 because the collaboration agreement with Merck was terminated in November 2012.

Consolidated gross margin for the three months and year ended December 31, 2013 was 60% and 59%, respectively. Consolidated gross margin for the three months and year ended December 31, 2012 was 60% and 63%, respectively. Gross margin for the current year was negatively impacted by higher royalties, an unfavorable change in product mix and the absence of the \$1.0 million HCV milestone payment, partially offset by an improvement in overhead absorption.

Consolidated operating expenses decreased to \$11.1 million during the fourth quarter of 2013 compared to \$19.4 million in the comparable period of 2012. For the year ended December 31, 2013, consolidated operating expenses were \$70.8 million, a decrease from the \$71.8 million reported for the year ended December 31, 2012. The decrease for the fourth quarter of 2013 was primarily due to the inclusion of the \$8.3 million Roche settlement payment partially offset by higher promotional and advertising expenses associated with the Company's OraQuick® In-Home HIV test. The current quarter and full-year period expenses included \$4.6 million and \$18.8 million of promotional and advertising costs related to this product, compared to \$5.2 million and \$9.9 million spent in the fourth quarter and full-year of 2012, respectively.

For the three months ended December 31, 2013, the Company recorded Canadian income tax expense of \$14,000. For the year ended December 31, 2013, the Company recorded a Canadian income tax benefit of \$772,000 associated with the loss before income taxes and certain Canadian research and development and investment tax credits at DNAG.

The Company's cash balance totaled \$93.2 million at December 31, 2013 compared to \$87.9 million at December 31, 2012. Working capital was \$100.6 million at December 31, 2013 compared to \$103.5 million at December 31, 2012. For the year ended December 31, 2013, the Company generated \$8.3 million from operations, which included the \$8.3 million settlement payment from Roche. Cash generated by operations in the fourth quarter of 2013 was \$11.4 million which also included the \$8.3 million Roche payment.

First Quarter 2014 Outlook

The Company expects consolidated net revenues to range from \$23.0 to \$23.5 million and is projecting a consolidated net loss of approximately \$0.13—\$0.14 per share for the first quarter of 2014.

Financial Data

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2013	2012	2013	2012
Results of Operations				
Net revenues(1)	\$28,768	\$22,144	\$ 98,940	\$ 87,820
Cost of products sold	11,640	8,893	40,351	32,249
Gross profit	17,128	13,251	58,589	55,571
Operating expenses:				
Research and development	2,212	2,893	10,932	12,445
Sales and marketing	11,241	11,597	46,465	37,087
General and administrative	5,912	4,911	21,654	22,309
Gain on contract termination settlement	(8,300)	—	(8,300)	—
Total operating expenses	11,065	19,401	70,751	71,841
Operating income (loss)	6,063	(6,150)	(12,162)	(16,270)
Other income (expense)	164	25	200	(242)
Income (loss) before income taxes	6,227	(6,125)	(11,962)	(16,512)
Income tax expense (benefit)	14	(259)	(772)	(1,397)
Net income (loss)	<u>\$ 6,213</u>	<u>\$ (5,866)</u>	<u>\$ (11,190)</u>	<u>\$ (15,115)</u>
Earnings (loss) per share:				
Basic and Diluted	<u>\$ 0.11</u>	<u>\$ (0.11)</u>	<u>\$ (0.20)</u>	<u>\$ (0.29)</u>
Weighted average shares:				
Basic	55,616	55,224	55,555	51,457
Diluted	56,176	55,224	55,555	51,457

- (1) The three months and year ended December 31, 2013 net revenues include a non-recurring net favorable \$2.5 million adjustment to account for a change in the Company's revenue recognition policy related to its OraQuick® In-Home HIV tests.

Summary of Revenues by Market and Product (Unaudited)

	Three Months Ended December 31,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2013	2012		2013	2012
Market					
Infectious disease testing	\$15,436	\$11,846	30%	54%	54%
Substance abuse testing	2,116	2,101	1	7	9
Cryosurgical systems	3,558	2,696	32	12	12
Molecular collection systems	6,831	4,266	60	24	19
Insurance risk assessment	827	1,037	(20)	3	5
Net product revenues	28,768	21,946	31	100	99
Licensing and product development	—	198	(100)	—	1
Net revenues	<u>\$28,768</u>	<u>\$22,144</u>	30%	<u>100%</u>	<u>100%</u>
	Year Ended December 31,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2013	2012		2013	2012
Market					
Infectious disease testing	\$50,961	\$42,728	19%	51%	49%
Substance abuse testing	8,571	9,407	(9)	9	11
Cryosurgical systems	14,468	14,876	(3)	14	17
Molecular collection systems	20,381	14,258	43	21	16
Insurance risk assessment	3,936	4,484	(12)	4	5
Net product revenues	98,317	85,753	15	99	98
Licensing and product development	623	2,067	(70)	1	2
Net revenues	<u>\$98,940</u>	<u>\$87,820</u>	13%	<u>100%</u>	<u>100%</u>

	Three Months Ended December 31,			Year Ended December 31,		
	2013	2012	% Change	2013	2012	% Change
OraQuick® Revenues						
Domestic HIV	\$ 8,447	\$ 9,157	(8)%	\$32,301	\$34,265	(6)%
International HIV	907	773	17	3,365	3,061	10
Domestic HIV OTC	3,909	546	616	9,106	546	1568
Net HIV revenues	13,263	10,476	27	44,772	37,872	18
Domestic HCV	1,073	847	27	2,847	2,805	1
International HCV	860	326	164	2,268	1,059	114
Net HCV revenues	1,933	1,173	65	5,115	3,864	32
Net OraQuick® revenues	\$15,196	\$11,649	30%	\$49,887	\$41,736	20%

	Three Months Ended December 31,			Year Ended December 31,		
	2013	2012	% Change	2013	2012	% Change
Intercept® Revenues						
Domestic	\$1,453	\$1,354	7%	\$5,693	\$6,335	(10)%
International	115	90	28	500	706	(29)
Net Intercept® revenues	\$1,568	\$1,444	9%	\$6,193	\$7,041	(12)%

	Three Months Ended December 31,			Year Ended December 31,		
	2013	2012	% Change	2013	2012	% Change
Cryosurgical Systems Revenues						
Domestic professional	\$1,828	\$1,818	1%	\$ 6,020	\$ 7,159	(16)%
International professional	402	352	14	1,441	1,462	(1)
International over-the-counter	1,328	526	152	7,007	6,255	12
Net cryosurgical systems revenues	\$3,558	\$2,696	32%	\$14,468	\$14,876	(3)%

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2013	December 31, 2012
Assets		
Cash	\$ 93,191	\$ 87,888
Accounts receivable, net	12,957	17,469
Inventories	11,444	12,758
Other current assets	1,983	2,002
Property and equipment, net	17,933	18,546
Intangible assets, net	22,226	27,207
Goodwill	23,782	25,445
Other non-current assets	729	124
Total assets	\$ 184,245	\$ 191,439

Liabilities and Stockholders' Equity

Accounts payable	\$ 4,834	\$ 3,380
Deferred revenue	1,119	5,504
Accrued expenses	13,032	7,750
Other non-current liabilities	677	89
Deferred income taxes	3,437	4,401
Stockholders' equity	161,146	170,315
Total liabilities and stockholders' equity	\$ 184,245	\$ 191,439

Additional Financial Data (Unaudited)

	Year ended December 31,	
	2013	2012
Capital expenditures	\$ 2,462	\$ 2,019
Net proceeds from public offering	\$ —	\$ 70,246
Depreciation and amortization	\$ 6,492	\$ 7,250
Stock based compensation	\$ 5,572	\$ 5,197
Cash provided by (used in) operating activities	\$ 8,286	\$ (5,373)

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2013 fourth quarter and full-year financial results, certain business developments and financial guidance for the first quarter of 2014, 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 #37105448 or go to OraSure Technologies' web site, www.orasure.com, and click on the Investor Relations page. Please click on the webcast link and follow the prompts for registration and access 10 minutes prior to the call. 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 12, 2014, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #37105448.

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. The Company sells the OraQuick® In-Home HIV Test, the first and only rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market 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 the Company, 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 our 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; ability to effectively resolve 483 observations, warning letters and other findings or comments from the FDA or other regulators; 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, historic purchase levels or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to

increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, 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 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 products and components; availability of related products produced by third parties or products required for use of the Company's 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 the Company's 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, 2012, 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.

OraSure Technologies, Inc.
2013 Fourth Quarter and Full Year
Analyst/Investor Conference Call
February 5, 2014

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.

About an hour ago we issued a press release in which we announced excellent fourth quarter results and a strong finish to a good year in 2013.

- Consolidated net revenues for the fourth quarter were almost \$29 million and total revenues for the year were just under \$100 million. Both are records for OraSure.
- The major growth drivers were our infectious disease and molecular collection systems businesses.
- Infectious disease revenues were up 30% for the quarter and 19% for the year, primarily because of sales of our OraQuick® In-Home HIV test and growth in our HCV business.
- Our molecular collection systems business continues to deliver exceptional results. Net revenues for this segment grew 60% in the fourth quarter and 43% for the full year, compared to 2012.

During the fourth quarter, we continued to execute our new marketing campaign for the OraQuick® In-Home HIV test, and our OraQuick® HCV business gained momentum. We also entered into a new strategic collaboration for our Intercept® substance abuse testing business, which we expect will help us resume growing this business. I will provide additional insight into these and other items later in the call.

But first let me turn the call over to Ron to recap our financial performance. Ron. . .

Fourth Quarter 2013 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our fourth quarter 2013 consolidated net revenues were \$28.8 million, compared to \$22.1 million reported in 2012. Our consolidated product revenues increased 31% as a result of higher sales of our molecular collection systems, infectious disease testing and cryosurgical systems products. These increases were partially offset by lower sales of our insurance risk assessment products.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, increased to a record high of \$6.8 million in the fourth quarter of 2013 compared to \$4.3 million in 2012. This 60% increase was the result of higher sales in the commercial market.

Our infectious disease testing revenues were \$15.4 million in the fourth quarter of 2013, compared to \$11.8 million in the fourth quarter of 2012. The overall 30% increase was primarily a result of \$3.9 million in net sales of our OraQuick® In-Home HIV test compared to \$546,000 in the fourth quarter of 2012, the period in which we began selling this product.

During the current quarter, gross sales of our OraQuick® In-Home HIV test were \$4.3 million which included a \$2.7 million adjustment made in December to account for a change in our revenue recognition policy related to this product.

Total gross sales were offset by \$349,000 in customer allowances, including cooperative advertising, cash discounts and other allowances. Net sales of this product included approximately \$101,000 of direct sales of our OraQuick® In-Home HIV test to public health customers.

Sales of our OraQuick® HCV professional product in the domestic and international markets increased 65%. International sales of our professional HCV test in the fourth quarter of 2013 increased to \$860,000 from \$326,000 in the same period last year primarily due to sales in support of a significant testing program with an international NGO. Higher demand in the domestic market contributed to the increase in sales of our HCV test in Q4 to \$1.1 million from \$847,000 in the prior year.

International HIV sales increased to \$907,000 in the fourth quarter of 2013 from \$773,000 in the fourth quarter of 2012. This increase was partially offset by a decline in domestic HIV revenues, which were down \$710,000, or 8%, due to reductions in government funding and the timing of customer purchases.

Fourth quarter 2013 cryosurgical revenues increased 32% to \$3.6 million from \$2.7 million in the fourth quarter of 2012, primarily as a result of higher OTC sales. OTC sales increased to \$1.3 million in the fourth quarter of 2013 from \$526,000 million in the fourth quarter of 2012. This increase was primarily the result of the timing of orders placed by both our Latin American and European distributors.

Insurance risk assessment revenues decreased to \$827,000 in the fourth quarter of 2013 from \$1.0 million as a result of reduced demand in the domestic life insurance markets as well as the adoption by some underwriters of a "Simplified Issues" policy.

Gross Margin – Ron Spair

Gross Margin for the quarter ended December 31, 2013 was flat when compared to the year ago quarter.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the fourth quarter of 2013 decreased to \$11.1 million during the fourth quarter of 2013 compared to \$19.4 million in the fourth quarter of 2012. The decrease was primarily due to the inclusion of an \$8.3 million settlement payment received from Roche Diagnostics for the termination of our oral fluid assay collaboration agreement. Advertising and promotional activities related to our OraQuick® In-Home HIV test also decreased to \$4.6 million in the fourth quarter of 2013, compared to \$5.2 million spent in the fourth quarter of 2012.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of \$6.2 million, or \$0.11 per share, for the fourth quarter of 2013, compared to a net loss of \$5.9 million, or \$0.11 per share, for the same period of 2012.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash balance at December 31, 2013 was \$93.2 million compared to \$87.9 million at December 31, 2012. Cash provided by operating activities in the fourth quarter of 2013 was \$11.4 million compared to \$1.4 million used in operating activities in the fourth quarter of 2012. Cash generated in the fourth quarter of 2013 included the \$8.3 million payment from Roche.

First Quarter 2014 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the first quarter of 2014, we are projecting consolidated net revenues of approximately \$23.0 to \$23.5 million and a consolidated net loss per share of approximately \$0.13 to \$0.14 for the quarter.

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

Business Update – Doug Michels

Thanks, Ron.

HIV-OTC – Doug Michels

The fourth quarter was the first full quarter of implementation of our new marketing campaign for the OraQuick® In-Home HIV test, entitled “Life. As We Know It.” This campaign, which launched in September in conjunction with National Gay Men’s HIV Awareness Day, has focused on the need to significantly increase brand awareness among MSM (men who have sex with men) and African American consumers. As explained in prior calls, this new campaign has targeted urban, high prevalence markets and has incorporated influential and trusted spokespeople from within the target communities we serve.

We are beginning to see positive results from this new campaign. Retail sales have increased over the last several periods, with average weekly sales to major retail accounts up about 7% in December vs. November of last year and up about 8% in January of 2014 vs. December 2013. Additionally, we believe that a greater portion of our sales are now coming from channels not tracked by the Nielsen Service, such as internet sites and independent drug stores. We estimate that these outlets represented at least 13% of our total retail sales and 24% of total product shipped during 2013.

In addition, social media mentions and website traffic increased significantly during the fourth quarter and continue to build in 2014.

- Daily visits to our OraQuick.com website since the launch of the new campaign are up about 10% compared to Q2 of 2013 and up about 82% compared to Q3 of 2013.

- Visitors to our website are showing strong purchase intent with about 40% indicating they will purchase at retail or online after their site visit.
- Average daily social media impressions, a key measure of the impact of our campaign, reached a record high in January of 1.1 million, which is an 80% increase over June 2013. We expect our marketing plan will continue to deliver increased levels of impressions and increased product sales as we work through the first quarter.

In January, we added a significant new element to the campaign with the launch of our sponsorship of the hit BET series, “Being Mary Jane,” which premiered on January 7. Being Mary Jane was the No. 1 original cable series debut for the 2013-2014 season among adults and women aged 18-49, with 5.2 million viewers tuning into the premiere night. Our sponsorship includes a custom TV commercial featuring journalist and TV personality Jackie Reed and digital advertising through BET properties.

We also launched the print element of our partnership with Essence Magazine with an advertorial in the February “Love” edition. We are continuing a strong digital program and will expand our reach with new properties throughout the first quarter of this year.

To reach gay men, we are continuing our LOGO TV partnership and look forward to our sponsorship of Rue Paul’s “Drag Race,” LOGO’s top rated show, beginning in February. This will be in addition to our digital programs and planned scheduled events targeting the gay community.

We also continue to work with our distinguished panels of influencers within our targeted communities, including Magic Johnson, Dr. Rachael Ross, Demetria Lucas, Jackie Reed, Ross Mathews and others. These celebrities are being used in advertising, public relations and social media.

The FDA recently issued new guidelines on social media that provide manufacturers greater liberty in the social media space. Although these guidelines were specifically written for the pharmaceutical sector, we believe the principles will be applied to manufacturers of medical devices. This change is expected to allow greater flexibility to take advantage of social media in the months ahead and utilize a higher proportion of unpaid media for our promotional activities.

As you may know, low product awareness among key consumer targets has been an issue. In December, we completed a study to measure awareness among the MSM community. Unaided product awareness among gay men is now 15% and aided awareness is 47%. This is an area we are working to further improve and we expect our new marketing campaign to aid in that effort. We plan to complete a similar study to measure awareness within the African American community in February.

Our In-Home HIV test also continues to receive strong support from the major retail chains, and we are making great strides in understanding how to maximize our impact in-store and leverage the power of our broad distribution. Starting in the first quarter of this year, we expect to launch several new retail programs. In January, we launched an innovative new program using the OraQuick® In-Home test and the retailers' distribution networks to assist public health entities in accessing hard-to-reach audiences. We will also launch our first major merchandising program, with display units planned in close to 2,000 high-volume retail outlets. These displays will increase visibility of the product in-store and ensure adequate inventory to support key promotions.

We will also continue to use a combination of tactics to attempt to reduce or remove barriers to consumer access at retail, although this remains a key challenge

as described in prior calls. These tactics include store level retail coverage to remove barriers and ensure product inventory, as well as the development and pilot of a theft allowance for retailers to encourage them to remove security devices. We expect to be able to measure the impact of these tactics more fully later in the first quarter.

Although the product is now only available domestically, global interest in our In-Home HIV test is growing, largely due to the public health benefit and positive experience seen here in the US. As an example, it is expected that the long-time ban on home HIV testing in the UK will be removed in or around April 2014. We have been approached regarding collaborations in Latin America, Europe, Asia and the Middle East and are currently conducting volumetric studies in several markets. We are also engaged in active discussions with government authorities, advocates and potential commercial partners in several international markets. We are increasingly optimistic about our prospects for international expansion.

OraQuick® HCV – Doug Michels

Turning next to our OraQuick® HCV test:

As discussed in prior calls, there have been a number of encouraging developments during the past year that we expect will positively impact demand for this product. First and foremost are the new therapies that are becoming available for the treatment of hepatitis C infection. In December of last year, Gilead Sciences received FDA approval for its sofosbuvir medication and AbbVie's CEO indicated on a recent earnings call that he expected the U.S. launch of AbbVie's new therapeutic to occur later in 2014. Other pharma companies such as Johnson & Johnson and Bristol-Meyers Squibb have similar drug approvals pending before the FDA. These treatments are expected to be more effective with fewer side effects and will likely drive demand for increased HCV testing.

During 2013, the US Preventive Services Task Force issued final recommendations giving HCV screening for both at-risk individuals and baby boomers a “B” grade. Any service receiving an “A” or “B” grade from the Task Force is expected to be covered by insurance without cost sharing. The “B” grade for screening baby boomers represents a significant step by the Task Force and brings its final recommendations into line with the CDC’s recommendations that all persons falling within the baby boomer birth cohort be tested at least once for HCV due to the higher risk of infection within that population.

On October 23, 2013, the State of New York passed a law requiring that doctors offer hepatitis C testing as a routine part of healthcare provided to baby boomers. The law went into effect on January 1, 2014. We believe this could be the start of a trend among the states and at least two, Pennsylvania and Florida, have introduced HCV testing legislation. We also believe similar legislation may be in the planning stages in Ohio, Maryland, Georgia and the District of Columbia.

Recently, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America issued updated guidance on HCV testing and linkage to care. This guidance recommends HCV antibody testing at least once for persons born between 1945 and 1965 and for other individuals who have been identified to have increased risk of HCV infection. Our OraQuick HCV test is specifically mentioned in the guidance as an FDA-approved antibody test that should be considered for this broad-based testing.

We are starting to see positive signs in our business, as evidenced by our most recent financial performance. Fourth quarter HCV revenues rose 65% over the year ago period with full-year revenues increasing 32% over 2012. These increases were driven by higher demand in the US and internationally. For the full-year 2013, we added over 400 new HCV customers, and we continue to see growth in the average order size for this product in all markets, both domestic and international.

As we look forward, we believe the recent market developments, and in particular the approval of new, more effective treatment therapies, will continue to drive demand for hepatitis C testing and the use of our test. We expect to see continued growth domestically especially as our public health customers expand existing testing programs and start new ones and as hospitals and physician offices more widely implement testing of baby boomers. International growth should continue as well as we expect continued purchases from the large NGO we began supplying in the second half of last year. We are also continuing discussions with the pharmaceutical companies offering treatment for HCV and we are enthusiastic about the prospects of working more closely with them to increase HCV testing and getting those individuals who are diagnosed the care that they need.

Molecular Collection Systems – Doug Michels

Another area I want to address is our molecular collections systems business. As Ron mentioned, this part of our business delivered record revenues for both the fourth quarter and full year and has been a key growth driver for the Company.

DNA Genotek's commercial business fueled this exceptional growth. This represents a shift in customer mix as DNA Genotek has historically received the majority of its revenues from academic customers. However, the revenue split between commercial and academic customers was approximately 80/20 for Q4 and for the total year was approximately 60/40. The business is continuing to see the benefits in the commercial market from having the only 510(k) cleared device for collecting and stabilizing DNA from saliva for genetic testing. These benefits are translating into longer-term purchasing agreements from some commercial customers, which are driving growth and predictability.

The company's investment in the academic market is also generating new opportunities. Although the US and European academic markets are still facing significant funding pressure, DNA Genotek continues to win new academic projects in both of those territories.

We have also spoken previously regarding efforts to increase DNA Genotek's production capacity. Those efforts are ongoing and on track. We expect to be ready with increased production capacity later in Q1 of 2014.

Before moving to the next topic, I want to briefly address the FDA warning letter received by 23andMe in late 2013. That letter resulted in 23andMe reducing the scope of its services in the US. Although these events will negatively affect sales at least in the near term, DNA Genotek continues to diversify its customer base. Consequently, we expect our molecular collection systems business to continue to grow in 2014.

Substance Abuse Testing – Doug Michels

During the fourth quarter we announced a significant development affecting our substance abuse testing business. We terminated our ongoing collaboration with Roche Diagnostics for the development of high throughput fully-automated oral fluid drugs-of-abuse assays for use with our Intercept® collection device. As part of the termination, we received an \$8.3 million payment and Roche has agreed to continue to supply a number of the assays that had previously received 510(k) clearance for up to a 5-year period.

At the same time, we announced that we had entered into a new agreement with Thermo Fisher for the development and supply of replacement fully-automated assays for this part of the business. We are very excited about this new relationship and expect to launch a NIDA-5 panel of the new assays later this year with our second generation Intercept® device into the criminal justice and forensics market. The ultimate plan is to obtain 510(k) clearance for up to 12 of the Thermo assays for use with our new Intercept® device and in the process meet the requirements promulgated under new oral fluid drug testing guidelines expected to be issued by SAMHSA. We believe this collaboration will have a significant beneficial impact on the Company and allow us to resume growth in our substance abuse testing business.

Management Change – Doug Michels

Before we open the floor up to your questions, I wanted to let you know about an upcoming change in our senior management team. Dr. Stephen Lee, our Executive Vice President, Research and Development and Chief Science Officer, has announced that he will be retiring from OraSure effective at the end of February. This was a personal decision that Steve has made and we have a plan in place for the orderly transition of his responsibilities.

Steve joined OraSure in 2005 and has made numerous contributions to our Company. Under Steve's leadership, OraSure obtained FDA approval of and commercially launched our OraQuick® HCV test, the first and only rapid HCV test approved by the FDA. He also played a critical role in the Company's highly successful efforts to develop and introduce the OraQuick® In-Home HIV test. On behalf of our management team and the Board of Directors, I would like to wish Steve all the best in his future endeavors.

As I mentioned previously, we have a transition plan in place for Steve's retirement. So today I am very pleased to announce the promotion of Dr. Eric Whitters from Director of Research and Development, to Senior Vice President of R&D, Regulatory, Quality and Clinical Affairs, effective March 1, 2014. Eric will take over Steve's responsibilities, will be a member of our internal Executive Committee and will report directly to me. Eric joined OraSure in November 2012 and has over 20 years of experience in the diagnostics industry. Before coming to OraSure, Eric served as Vice President, Research and Development at Novartis Diagnostics and as a Director of Technical Operations at Siemens Healthcare Diagnostics. Eric has particular expertise and experience in molecular diagnostics, which is certainly an important growth opportunity for the Company. I look forward to the many contributions Eric will undoubtedly make to our Company's future success.

Conclusion

So, with 2013 now complete, we intend to build on the strong momentum from the fourth quarter. OraSure has ample opportunities to grow in 2014 as we are in the early stages of penetration in several large markets. We expect that growth to be driven primarily by our molecular collection systems and rapid HCV testing businesses as well as our In-Home HIV product. We also expect to see some benefit in the substance abuse area from our new collaboration with Thermo Fisher later in the year.

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

[Q&A session]

Final 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 our 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; inventory levels at distributors and other customers; ability to market and sell products, whether through our 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; ability to effectively resolve 483 observations, warning letters and other findings or comments from the FDA or other regulators; 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, historic purchase levels or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, 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 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 products and components; availability of related products produced by third parties or products required for use of the Company's 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 the Company's 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, 2012, 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.