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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 4, 2015**

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**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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**

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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 4, 2015, 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, 2014, and providing financial guidance for the first quarter of 2015. 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 4, 2015, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, President and Chief Executive Officer, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer, discussed the Company’s consolidated financial results for the quarter and full year ended December 31, 2014, provided financial guidance for the first quarter of 2015 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 4, 2015, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31, 2014, and providing financial guidance for the first quarter of 2015.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2014 Analyst/Investor Conference Call Held February 4, 2015.

**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 4, 2015

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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**OraSure Announces Full-Year and Fourth Quarter 2014 Financial Results**

*—2014 Revenues Exceed \$100 million—*

**BETHLEHEM, PA** – February 4, 2015 – (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 ended December 31, 2014.

**Financial Highlights**

- The Company exceeded \$100 million in annual revenues for the first time in its history. Consolidated net revenues for the year ended December 31, 2014 were \$106.5 million, an 8% increase from the comparable period of 2013.
- Consolidated net revenues for the fourth quarter of 2014 were \$28.7 million, which approximated the level of revenues reported in the fourth quarter of 2013.
- Licensing and product development revenues were \$3.4 million and \$7.6 million for the quarter and year ended December 31, 2014, respectively, and represent the recognition of payments under the Company's HCV collaboration with AbbVie.
- Net revenues generated by the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), were \$6.3 million and \$23.8 million for the fourth quarter and full-year of 2014, respectively, representing an 8% decrease and a 17% increase over the fourth quarter and full-year of 2013, respectively. DNAG accounted for 22% of the Company's aggregate 2014 consolidated net revenues.

- Net revenues for the Company's OraQuick® rapid HCV test were \$1.7 million and \$7.3 million for the fourth quarter and full-year of 2014, respectively, representing a 10% decrease and a 42% increase over the fourth quarter and full-year of 2013, respectively.
- Consolidated net loss for the fourth quarter of 2014 was \$2.7 million, or \$0.05 per share, which compares to net income of \$6.2 million, or \$0.11 per share, for the fourth quarter of 2013. This change in the current quarter bottom line performance was primarily the result of the absence of an \$8.3 million contract termination payment received in the prior year period. Consolidated net loss for the year ended December 31, 2014 was \$4.6 million, or \$0.08 per share, which compares to a net loss of \$11.2 million, or \$0.20 per share, for the comparable period of 2013.
- Cash and short term investments totaled \$97.9 million and working capital amounted to \$104.8 million at December 31, 2014.

“Crossing the \$100 million threshold in annual revenues has been a long-term goal and is a significant milestone for our Company,” said Douglas A. Michels, President and CEO of OraSure Technologies. “The molecular collection systems segment continues to deliver strong results and our HCV business continues to grow. Our immediate focus is on increasing usage of our OraQuick® HCV test under our HCV collaboration with AbbVie, continuing the strong performance at DNA Genotek, and pursuing a potential rapid Ebola test, including securing development funding and purchase commitments for this proposed new product.”

## Financial Results

Consolidated net product revenues for the fourth quarter of 2014 decreased 12% from the comparable period of 2013, primarily as a result of the change in revenue recognition policy related to the Company's OraQuick® In-Home HIV test which increased fourth quarter 2013 net revenues by \$2.5 million. Consolidated net product revenues for the year ended December 31, 2014 increased 1% over the prior year period, primarily as a result of higher sales of the Company's molecular collection systems, OraQuick® HCV and cryosurgical systems products. These increases were partially offset by lower sales of the OraQuick® professional HIV product line and OraQuick® In-Home HIV test. OraQuick® HIV In-Home revenues in 2013 included the \$2.5 million non-recurring favorable adjustment resulting from the accounting policy change.

Consolidated licensing and product development revenues for the fourth quarter and full-year of 2014 were \$3.4 million and \$7.6 million, respectively. Consolidated licensing and product development revenues for the fourth quarter and full-year of 2013 were \$0 and \$623,000, respectively. Licensing and product development revenues in 2014 represent the recognition of exclusivity payments under the Company's HCV collaboration agreement with AbbVie. Licensing and product

development revenues in 2013 represent royalties paid on domestic outsales of a licensee's OTC cryosurgical wart removal product, pursuant to a license agreement that expired in that same year.

Consolidated gross margin for both the three months and year ended December 31, 2014 was 63%. Consolidated gross margin for the three months and year ended December 31, 2013 was 60% and 59%, respectively. Gross margin for the current quarter improved largely as a result of the increased licensing and product development revenues and a more favorable product mix resulting from higher margin DNAG sales, partially offset by a decline in overhead absorption as a result of facility equipment replacements. Gross margin for the full-year 2014 also improved largely due to the increased licensing and product development revenues and higher margin DNAG sales.

Consolidated operating expenses increased to \$20.5 million during the fourth quarter of 2014 compared to \$11.1 million in the comparable period of 2013. This increase was primarily due to the absence of an \$8.3 million contract termination payment from Roche Diagnostics which was received in the fourth quarter of 2013. This payment, coupled with lower promotional expenses associated with the Company's OraQuick® In-Home HIV test, were partially offset by increased expenses incurred under the HCV collaboration with AbbVie, higher research and development costs and higher staffing expenses. Promotional expenses for the OraQuick® In-Home HIV test were \$614,000 and \$4.6 million for the fourth quarters of 2014 and 2013, respectively.

For the year ended December 31, 2014, consolidated operating expenses increased to \$71.4 million from the \$70.8 million reported for the prior year. This increase was primarily due to a \$2.8 million reduction in contract termination payments received from Roche Diagnostics during 2014, increased expenses incurred under the HCV collaboration with AbbVie, higher research and development costs, and higher legal, staffing and consulting costs, partially offset by lower promotional expenses associated with the Company's OraQuick® In-Home HIV test. Full-year promotional expenses for the OraQuick® In-Home HIV test were \$8.5 million and \$18.8 million for 2014 and 2013, respectively.

For the three months and year ended December 31, 2014, the Company recorded Canadian income tax expense of \$376,000 and \$343,000, respectively. For the three months and year ended December 31, 2013, the Company recorded Canadian income tax expense of \$14,000 and a Canadian income tax benefit of \$772,000 respectively. The 2013 full-year tax benefit was the result of certain Canadian research and development and investment tax credits and DNAG's loss before income taxes in that period.

The Company's cash and short-term investment balance totaled \$97.9 million at December 31, 2014 compared to \$93.2 million in cash at December 31, 2013. Working capital was \$104.8 million at December 31, 2014 compared to \$100.6 million at December 31, 2013. For the year ended December 31, 2014, the Company's consolidated operations generated \$7.5 million of cash.

## First Quarter 2015 Outlook

The Company expects consolidated net revenues to range from \$26.5 to \$27.0 million and is projecting a consolidated net loss of approximately \$0.01 to \$0.02 per share for the first quarter of 2015.

## Financial Data

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

#### Unaudited

	Three months ended December 31,		Year ended December 31,	
	2014	2013	2014	2013
<b>Results of Operations</b>				
Net revenues <sup>1</sup>	\$28,681	\$28,768	\$106,464	\$ 98,940
Cost of products sold	10,704	11,640	39,840	40,351
Gross profit	17,977	17,128	66,624	58,589
Operating expenses:				
Research and development	3,817	2,212	12,058	10,932
Sales and marketing	10,290	11,241	41,118	46,465
General and administrative	6,433	5,912	23,750	21,654
Gain on contract termination settlement	—	(8,300)	(5,500)	(8,300)
Total operating expenses	20,540	11,065	71,426	70,751
Operating income (loss)	(2,563)	6,063	(4,802)	(12,162)
Other income (expense)	287	164	531	200
Income (loss) before income taxes	(2,276)	6,227	(4,271)	(11,962)
Income tax expense (benefit)	376	14	343	(772)
Net income (loss)	<u>\$ (2,652)</u>	<u>\$ 6,213</u>	<u>\$ (4,614)</u>	<u>\$ (11,190)</u>
Earnings (loss) per share:				
Basic and Diluted	<u>\$ (0.05)</u>	<u>\$ 0.11</u>	<u>\$ (0.08)</u>	<u>\$ (0.20)</u>
Weighted average shares:				
Basic	<u>56,105</u>	<u>55,616</u>	<u>55,949</u>	<u>55,555</u>
Diluted	<u>56,105</u>	<u>56,176</u>	<u>55,949</u>	<u>55,555</u>

<sup>1</sup> Net revenues for the three months and year ended December 31, 2013 include a non-recurring net favorable \$2.5 million adjustment to reflect a change in the Company's revenue recognition policy related to its OraQuick® In-Home HIV test.



**Summary of Net Revenues by Market and Product (Unaudited)**

	Three Months Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2014	2013	% Change	2014	2013
<b>Market</b>					
Infectious disease testing	\$12,602	\$15,436	(18)%	44%	54%
Substance abuse testing	2,250	2,116	6	8	7
Cryosurgical systems	3,377	3,558	(5)	11	12
Molecular collection systems	6,255	6,831	(8)	22	24
Insurance risk assessment	800	827	(3)	3	3
Net product revenues	25,284	28,768	(12)	88	100
Licensing and product development	3,397	—	NM*	12	—
Net revenues	<u>\$28,681</u>	<u>\$28,768</u>	(0)%	<u>100%</u>	<u>100%</u>

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
	2014	2013	% Change	2014	2013
<b>Market</b>					
Infectious disease testing	\$ 47,515	\$50,961	(7)%	45%	51%
Substance abuse testing	8,437	8,571	(2)	8	9
Cryosurgical systems	15,505	14,468	7	15	14
Molecular collection systems	23,778	20,381	17	22	21
Insurance risk assessment	3,659	3,936	(7)	3	4
Net product revenues	98,894	98,317	1	93	99
Licensing and product development	7,570	623	NM*	7	1
Net revenues	<u>\$106,464</u>	<u>\$98,940</u>	8%	<u>100%</u>	<u>100%</u>

\* Calculation is not considered meaningful

	Three Months Ended December 31,			Year Ended December 31,		
	2014	2013	% Change	2014	2013	% Change
<b>OraQuick® Revenues</b>						
Domestic HIV	\$ 8,363	\$ 8,447	(1)%	\$29,933	\$32,301	(7)%
International HIV	587	907	(35)	2,483	3,365	(26)
Domestic HIV OTC <sup>1</sup>	1,502	3,909	(62)	6,493	9,106	(29)
Net HIV revenues	10,452	13,263	(21)	38,909	44,772	(13)
Domestic HCV	1,036	1,073	(3)	4,220	2,847	48
International HCV	707	860	(18)	3,048	2,268	34
Net HCV revenues	1,743	1,933	(10)	7,268	5,115	42
Net OraQuick® revenues	\$12,195	\$15,196	(20)%	\$46,177	\$49,887	(7)%

	Three Months Ended December 31,			Year Ended December 31,		
	2014	2013	% Change	2014	2013	% Change
<b>Intercept® Revenues</b>						
Domestic	\$1,629	\$1,453	12%	\$6,101	\$5,693	7%
International	73	115	(37)	149	500	(70)
Net Intercept® revenues	\$1,702	\$1,568	9%	\$6,250	\$6,193	1%

	Three Months Ended December 31,			Year Ended December 31,		
	2014	2013	% Change	2014	2013	% Change
<b>Cryosurgical Systems Revenues</b>						
Domestic professional	\$2,149	\$1,828	18%	\$ 6,750	\$ 6,020	12%
International professional	111	402	(72)	693	1,441	(52)
Domestic over-the-counter	108	—	100	108	—	100
International over-the-counter	1,009	1,328	(24)	7,954	7,007	14
Net cryosurgical systems revenues	\$3,377	\$3,558	(5)%	\$15,505	\$14,468	7%

<sup>1</sup> Net revenues for the three months and year ended December 31, 2013 include a non-recurring net favorable \$2.5 million adjustment to reflect a change in the Company's revenue recognition policy related to its OraQuick® In-Home HIV test.

**Condensed Consolidated Balance Sheets (Unaudited)**

	<u>December 31, 2014</u>	<u>December 31, 2013</u>
<u>Assets</u>		
Cash	\$ 92,867	\$ 93,191
Short-term investments	5,000	—
Accounts receivable, net	16,138	12,957
Inventories	15,763	11,444
Other current assets	1,446	1,983
Property and equipment, net	17,934	17,933
Intangible assets, net	17,505	22,226
Goodwill	21,734	23,782
Other non-current assets	1,246	729
Total assets	<u>\$ 189,633</u>	<u>\$ 184,245</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 7,148	\$ 4,834
Deferred revenue	8,043	1,119
Accrued expenses	11,271	13,032
Other non-current liabilities	1,234	677
Deferred income taxes	3,236	3,437
Stockholders' equity	158,701	161,146
Total liabilities and stockholders' equity	<u>\$ 189,633</u>	<u>\$ 184,245</u>

	<u>Year ended</u> <u>December 31,</u>	
	<u>2014</u>	<u>2013</u>
<b>Additional Financial Data (Unaudited)</b>		
Capital expenditures	\$3,005	\$2,462
Depreciation and amortization	\$6,307	\$6,552
Stock based compensation	\$5,744	\$5,572
Cash provided by operating activities	\$7,526	\$8,385

**Conference Call**

The Company will host a conference call and audio webcast to discuss the Company's 2014 full-year and fourth quarter financial results, certain business developments and financial guidance for the first quarter of 2015, 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, and Ronald H. Spair, Chief Financial Officer and Chief Operating Officer. 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 844-831-3030 (Domestic) or 315-625-6887 (International) and reference Conference ID #63824420 or go to OraSure Technologies' web site, [www.orasure.com](http://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 11, 2015, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #63824420.

### **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](http://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 warning letters, audit observations 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; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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, including changes in CDC or other testing guidelines, algorithms or other recommendations; 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 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 OraSure'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 attract and 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, 2013, 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.  
2014 Full Year and Fourth Quarter  
Analyst/Investor Conference Call  
February 4, 2015

**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 Rena. Good afternoon everyone and welcome to our call.

We had a very active fourth quarter advancing our HCV rapid testing programs, our molecular testing business and our Ebola development program. The Company's fourth quarter results exceeded our guidance on the top line and fell within our guidance for the bottom line.

Overall, 2014 was a very successful year. We had several noteworthy accomplishments, delivered solid financial performance and advanced many programs that we expect to drive our future results.

- For the first time in our history, annual revenues exceeded \$100 million.
- Our molecular collection systems business delivered strong growth in 2014 and ended the year up 17% over the prior year. This increasingly important part of our business accounts for over 20% of our annual consolidated net revenues.
- We entered into an important HCV co-promotion agreement with AbbVie last year. We believe this is a “first-of-its-kind” collaboration between a diagnostics company and pharmaceutical company and provides us with a significant opportunity to realize the full value of our rapid HCV test and accelerate growth of our HCV business.

- Our OraQuick® HCV test continued to gain momentum, with 2014 product sales of \$7.3 million. This represents a 42% increase over 2013. These revenues, coupled with the exclusivity payments received from AbbVie, resulted in total HCV-related revenues of \$14.8 million in 2014.
- During the year, we also instituted a new promotional strategy for our OraQuick® In-Home test designed to bring this product to profitability. We generated almost \$6.5 million in sales in 2014 and the adjustments we made to our strategy are expected to transition this product to profitability in 2015.
- Our revenue growth in 2014 and prior years, coupled with continued cost management, has substantially improved our bottom line performance. In 2014 alone, we reduced our operating loss by 61% and over the past three fiscal years this reduction was 71%. One significant by-product of this improved performance is that we ended 2014 with almost \$100 million in cash which we can use to further grow our business.

I would also point out the benefits we have realized by diversifying our product offerings. In 2014, our newest product lines, consisting of DNA Genotek, our HCV business and our In-Home HIV test, generated total net revenues of \$45 million, or 42% of our annual consolidated net revenues.

Later in the call, I will discuss in further detail our HCV collaboration activities with AbbVie, developments at DNA Genotek, and the recent launch of our new Intercept® collector along with a panel of high throughput drug assays. I will also briefly comment on our progress in developing our newest potential product, a rapid point-of-care test for Ebola on our OraQuick® platform.

So with that introduction, let me turn the call over to Ron for his financial review of the fourth quarter.

**Fourth Quarter 2014 Financial Results – Ron Spair**

Thanks Doug, and good afternoon everyone.

**Revenues – Ron Spair**

Our fourth quarter 2014 consolidated net revenues were \$28.7 million, compared to \$28.8 million reported in 2013. Our consolidated product revenues of \$25.3 million decreased 12% largely as a result of the change in revenue recognition policy related to our OraQuick® In-Home HIV test, which increased fourth quarter 2013 revenues by \$2.5 million. You may recall that we transitioned to the “sell-in” versus “sell-through” model of revenue recognition in Q4 2013. Without that adjustment, total revenues were up 9% quarter over quarter.

Licensing and product development revenues were \$3.4 million in the current quarter and represent the recognition of exclusivity payments under the AbbVie agreement. There were no comparable licensing and product development revenues in the fourth quarter of 2013.

Our overall infectious disease testing revenues decreased 2% in the fourth quarter of 2014, compared to the fourth quarter of 2013, after eliminating the \$2.5 million HIV-OTC revenue adjustment.

Sales of our OraQuick® HCV professional product in the domestic market decreased 3% in Q4 to \$1.0 million from \$1.1 million in the prior year. This decrease is largely due to the timing of orders placed by our public health customers. International sales of our HCV test in the fourth quarter of 2014 decreased to \$707,000 from \$860,000 in the same period last year, primarily due to reduced sales in support of a testing program with an international NGO.



Domestic sales of our professional HIV product were \$8.4 million in the fourth quarter of 2014, which were largely unchanged from the fourth quarter of 2013.

International sales of our professional HIV product were \$587,000 in the fourth quarter of 2014 compared to \$907,000 in the fourth quarter of 2013. This change was primarily due to an order received in the fourth quarter of 2013 from a Mexican customer that did not repeat in 2014.

During the current quarter, net sales of our OraQuick® In-Home HIV test were \$1.5 million compared to \$3.9 million in the fourth quarter of 2013. Excluding the \$2.5 million accounting adjustment, sales of this product increased 7% largely as a result of higher sales to our distributors and small retail accounts.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, decreased to \$6.3 million in the fourth quarter of 2014 compared to \$6.8 million in the fourth quarter of 2013. This 8% decrease was the result of approximately \$1.9 million in lower sales to 23andMe, partially offset by higher sales in the academic markets. Sales to DNA Genotek's other customers grew 34% in the current quarter and substantially offset the lower sales to 23andMe.

Fourth quarter 2014 cryosurgical revenues decreased 5% to \$3.4 million from \$3.6 million in the fourth quarter of 2013, primarily as a result of lower sales of our professional and OTC products in the international markets, partially offset by higher professional and OTC sales in the United States.

Substance abuse testing revenues increased to \$2.3 million in the fourth quarter of 2014 compared to \$2.1 million in 2013. This increase is largely due to higher sales of our Intercept® device as a result of ordering patterns and market growth due to improved economic conditions and increased interest in oral fluid testing.

**Gross Margin – Ron Spair**

Gross margin for the fourth quarter of 2014 was 63% compared to 60% reported for the fourth quarter of 2013. The current quarter margin benefited primarily from the \$3.4 million of licensing and product development revenues recognized from our AbbVie relationship as well as a more favorable product mix driven largely by increased DNAG sales to higher margin customers. These improvements in margin were partially offset by a decline in overhead absorption for the quarter as a result of manufacturing downtime associated with facility equipment replacements.

**Operating Expenses – Ron Spair**

Our consolidated operating expenses for the fourth quarter of 2014 increased to \$20.5 million compared to \$11.1 million in the fourth quarter of 2013. This increase was primarily due to the absence of an \$8.3 million contract termination payment from Roche Diagnostics which was received in the fourth quarter of 2013. This payment, coupled with lower promotional expenses associated with our OraQuick® In-Home HIV test, were partially offset by increased expenses incurred under the HCV agreement with AbbVie, higher R&D costs and higher staffing expenses.

**Net Income – Ron Spair**

From a bottom line perspective, we reported a net loss of \$2.7 million, or \$0.05 per share, for the fourth quarter of 2014, compared to net income of \$6.2 million, or \$0.11 per share, on a fully diluted basis, for the same period of 2013.

**Cash Flow from Operations and Liquidity – Ron Spair**

Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and short-term investment balance at December 31, 2014 was \$97.9 million compared to \$93.2 million at December 31, 2013. Cash used by operating activities in the fourth quarter of 2014 was \$858,000 compared to \$11.5 million generated in the fourth quarter of 2013, which benefited from the \$8.3 million payment from Roche.

**First Quarter 2015 Consolidated Financial Guidance – Ron Spair**

Turning to guidance for the first quarter of 2015, we are projecting consolidated net revenues of approximately \$26.5 to \$27.0 million and a consolidated net loss per share of approximately \$0.01 to \$0.02 for the quarter.

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

**Business Update – Doug Michels**

Thanks, Ron.

**OraQuick® HCV – Doug Michels**

As you know, our HCV business has been and will continue to be an important growth driver for the Company. A major component of this business is our co-promotion agreement with AbbVie, which is organized around several principal initiatives.

The largest initiative, and the one to which we and AbbVie are devoting most of our resources, is focused on primary care and specialty physicians. During the past several months, the AbbVie sales force has continued detailing our OraQuick® HCV test to physicians around the country. At the same time, we have also been promoting our HCV test primarily through several large med-surg distributors and manufacturer representative organizations, or MROs. As a result of these efforts, approximately 2,200 physicians, encompassing more than 1,700 practices, have indicated a strong interest in the product and a desire to be trained on its use. These accounts are split approximately 40% gastroenterologists and 60% general practitioners and other specialists.

Interest in our test is broad among the physicians we have contacted. We also are finding that the AbbVie Patient Support Program is viewed positively by the physicians who have reviewed it. Over 1,200 healthcare providers are trained or scheduled to be trained on our product and over 600 physician practices have actually received training and either have started purchasing product or are in the process of deciding whether to purchase and use the test.

Our experience over the past several months is that the final decision by a physician to offer our test and the AbbVie Patient Support Program is difficult to predict. Our initial estimate, based on our prior experience selling the OraQuick® HCV test to physicians, was that it would take from six to eight weeks from the time a physician's office initially expresses interest, completes training and makes a purchase decision. Our experience to date indicates that this process is taking a bit longer than expected. We and AbbVie are continuing to adjust and refine our tactics to help accelerate this decision making process where possible.

A second primary initiative is focused on commercial long-haul truck drivers. Working with two organizations dedicated to improving the health and wellness of professional truck drivers, we conducted four testing and awareness development

events last year. Some limited testing was completed at these events and indicated prevalence rates higher than the general population, as we expected. Although these results are preliminary, they confirm the importance of building awareness and implementing testing programs for truckers in 2015.

In November, we formed an advisory board consisting of fleet representatives, individuals representing independent truck drivers and industry consultants in order to obtain additional guidance on strategic and tactical planning for this initiative. We gained insights into how to educate truckers, the potential environments for testing and the concerns of the industry with the high cost of treatment for individuals who test positive for HCV. We will continue to do more work in these areas during the first quarter as we develop and refine our plans. Working closely with AbbVie and our industry partners, we intend to complete development of a provider portal and trucker “app” designed to provide education and awareness about the disease and the need to get tested. The next major truck testing event will be at the Mid-America Trucking Show to be held in Kentucky at the end of March.

A third market initiative is focused on national and regional retail pharmacies and retail clinics. Together with AbbVie, we have continued our discussions with a growing number of retail clinics and specialty pharmacies regarding the role they can play in expanding HCV awareness and testing. At the same time, we are planning for, and in the next few months we expect to initiate, pilot programs with two national retailers and one regional retail chain with the goal of developing sustainable models for offering rapid HCV testing and AbbVie’s Patient Support Program through their retail outlets. The discussions we have had with retailers to date have been encouraging. We expect the financial impact of the upcoming pilots to be realized in the second half of 2015.

Overall, we remain confident that our efforts with AbbVie will help educate many individuals on the importance of knowing their HCV status and the need to get tested. We also believe we have the right focus and resources to successfully execute on our initiatives under this important collaboration.

Apart from the AbbVie collaboration, our existing HCV business continues to grow. We shipped product to over 1,000 customers during 2014, with over two-thirds of our shipments being delivered to repeat customers. We also added over 300 new customers during this period. The 42% revenue growth in 2014 reflects the results of a lot of hard work and we believe this is the beginning of a longer-term growth trend for this product line.

**Molecular Collection Systems – Doug Michels**

A second area I want to address is our molecular collection systems business. We are very pleased with the continued excellent performance by DNA Genotek.

While total revenue for Q4 declined compared to the same quarter in 2013, this reduction was entirely due to lower year-over-year sales to a single large customer, 23andMe. Total DNA Genotek revenue for Q4 was down approximately \$600,000 from the prior year's quarter despite a \$1.9 million net revenue decline from 23andMe. As Ron stated, sales to DNA Genotek's other academic and commercial customers actually grew 34% in Q4 2014 and almost completely offset the reduction from this one large customer.

For the quarter, DNA Genotek's academic revenue was up 15%, reflecting strong sales of our Oragene product. The company had particularly strong quarterly sales in the UK, generating over \$1 million of orders from UK-based academic institutions in December alone, and continued to sell to academic institutions running studies in human genetics in many other countries.

We are also pleased with the continued progress in DNA Genotek's commercial business. In Q4, the company experienced continued strong sales to our largest commercial customers who use the company's technologies for pharmacogenomics testing. We also picked up several new commercial customers in Q4 and we expect those customers to purchase increasing volumes going forward.

You are all aware that 23andMe is working to clear its Personal Genome Service test with the FDA. Although I cannot comment directly on this regulatory process, I want to emphasize that we are doing everything possible to support their efforts. In the face of these regulatory challenges, however, we are impressed with 23andMe's business progress, including global business expansion in the second half of 2014 and some recent business expansion announcements in Q1 of this year. We look forward to continuing our strong relationship with 23andMe for many years.

**Substance Abuse Testing – Doug Michels**

Turning to our substance abuse testing business, our program to commercialize high throughput drug assays with our new Intercept® collector is progressing nicely.

I am pleased to report that we recently launched six high throughput, fully-automated oral fluid assays along with our new Intercept® i2 collector into the unregulated criminal justice and drug treatment markets. These assays consist of a "NIDA-5" panel for the detection of amphetamines, methamphetamines, cocaine, opiates, PCP and THC, or marijuana. We expect to launch a second group of six additional assays into these markets sometime in the second half of this year. This will result in a menu of 12 high throughput assays eventually being offered with an i2 device, which we believe will meet the needs of our customers.

We are also working to complete the appropriate 510(k) submissions for these products as quickly as possible. We expect to submit filings for all 12 assays along with our i2 collector later this year. Assuming we meet that deadline, we expect to receive clearances and begin commercial sales into the workplace testing and other regulated markets during 2016.

**Rapid Ebola Test – Doug Michels**

The last topic I will cover is the development and possible commercialization of a rapid test for Ebola. During the past several months, we achieved significant clinical and product development milestones and have substantially advanced our development program. We are very close to finalizing the design on a prototype device which would be available for field testing in Africa, subject to receipt of external funding. Early indications from testing by the Centers for Disease Control suggest that our prototype test can provide very good performance when evaluated on whole blood samples. We are highly encouraged by these results and hope to continue evaluating the device in more extensive clinical investigations.

Despite the good progress we have made on the development front, whether this product will ultimately contribute to our business depends on a number of factors. First, we are seeking funding for our development efforts from a variety of Federal agencies. The costs to complete development and obtain the regulatory approvals needed to build this product into a real business are not insignificant. We anticipate a positive response from one or more of these agencies and expect to hear back from them shortly. As we complete our clinical development and prepare for field testing, we are also in discussions with various government agencies regarding product procurement. Our goal is to obtain external development funding along with substantial and sustainable product purchase commitments. However, should we be unsuccessful in achieving one or both of these objectives, we will likely discontinue our work on this project.



**Conclusion**

So, as you've just heard, there are many growth opportunities on the table for the Company, and we are keenly focused on the successful execution of all of the initiatives I have outlined today. We are excited about the Company's prospects and we look forward to delivering a successful 2015, including full year profitability.

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; ability to effectively resolve warning letters, audit observations 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; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our 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, including changes in CDC or other testing guidelines, algorithms or other recommendations; 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 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 OraSure'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 attract and 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, 2013, 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 Report, and we undertake no duty to update these statements.