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 3, 2016

OraSure Technologies, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-16537**	**36-4370966**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(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 3, 2016, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2015, and providing financial guidance for the first quarter of 2016. 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.

The Company's Long-Term Incentive Policy (the "LTIP") provides for annual long-term incentive equity awards for the Company's senior management, including the Company's principal executive officer, principal financial officer and other named executive officers (the "NEO's"). Pursuant to the LTIP, on February 1, 2016, annual awards to the NEOs were granted by the Compensation Committee ("the "Committee") of the Company's Board of Directors (the "Board"), based on the performance of each NEO during 2015 ("Annual Awards"). These Annual Awards consisted of fifty percent (50%) performance-vested restricted units ("Performance Units") and fifty percent (50%) time-vested restricted stock ("Restricted Stock"). The value of these Annual Awards is as follows, in accordance with the LTIP:

	NEO	2016 Annual Award Value			
Name	Title	Restricted Stock	Performance Units	Total $	Total % Base Salary
Douglas A. Michels	President and Chief Executive Officer	$641,662	$ 641,662	$1,283,324	215%
Ronald H. Spair	Chief Financial Officer and Chief Operating Officer	$316,466	$ 316,466	$ 632,932	135%
Anthony Zezzo, II	Executive Vice President, Marketing and Sales	$172,805	$ 172,805	$ 345,610	90%
Jack E. Jerrett	Senior Vice President, General Counsel and Secretary	$129,150	$ 129,150	$ 258,300	75%
Mark L. Kuna	Senior Vice President, Finance, Controller and Assistant Secretary	$107,738	$ 107,738	$ 215,476	80%

The Performance Units will vest if (i) the recipient remains employed by the Company for three years following the date of grant and (ii) the performance criteria determined by the Committee and/or Board are met. The Restricted Stock will vest in equal annual installments over the three-year period following the grant date, subject to the recipient's continued employment by the Company.

For each award of Performance Units, one-half of that portion of the award shall be earned based on achievement of a three-year compound annual growth rate ("CAGR") target for consolidated product revenues for the fiscal year period 2016-2018 and the remaining half shall be earned based on achievement of a one-year adjusted earnings per share ("EPS") target for the fiscal year 2016. Both the product revenue CAGR and adjusted EPS targets exclude the impact of any potential acquisitions or divestitures by the Company. In addition, the adjusted EPS target excludes material changes in foreign exchange rates, new legal proceedings and certain other unbudgeted events unrelated to the Company's operations.

Vesting of both the Restricted Stock and Performance Units will be accelerated upon a change of control or in the event of the death or disability of the recipient, with the Performance Units vesting at target performance levels if the event occurs prior to the end of a performance period or at actual levels when a performance measure has already been met, as determined by the Committee or Board. In addition, where the recipient is terminated without cause, the Performance Units will vest on a pro-rata basis through the date of termination, with the vesting at target performance levels if the termination occurs prior to the end of a performance period or at actual levels when a performance measure has already been met, as determined by the Committee or Board. The Annual Awards for the NEOs will be subject to the additional or different vesting provisions and other terms of applicable employment agreements with each executive as well as the Company's standard terms and conditions for equity awards.

Item 7.01 – Regulation FD Disclosure.

On February 3, 2016, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company's President and Chief Executive Officer, and Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, discussed the Company's consolidated financial results for the quarter and full year ended December 31, 2015, provided financial guidance for the first quarter of 2016 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

Exhibit Number	Description
99.1	Press Release, dated February 3, 2016, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31 2015, and providing financial guidance for the first quarter of 2016.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full Year 2015 Analyst/ Investor Conference Call Held February 3, 2016.

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 3, 2016

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

Index to Exhibits

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Exhibit 99.1

OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces Record Revenues for Full-Year and Fourth Quarter 2015

BETHLEHEM, PA – February 3, 2016 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the full-year and fourth quarter ended December 31, 2015.

Financial Highlights

- Consolidated net revenues for the fourth quarter of 2015 were $32.4 million, a 13% increase from the fourth quarter of 2014. Consolidated net revenues for the year ended December 31, 2015 were $119.7 million, a 12% increase from 2014.
- The Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), contributed $7.8 million in net revenues during the fourth quarter of 2015, which represents a 24% increase over the fourth quarter of 2014. Net revenues from this segment for the full-year of 2015 were $29.9 million, a 26% increase from 2014.
- Net domestic revenues from sales of the Company's OraQuick® rapid HCV test were $2.7 million for the fourth quarter of 2015, representing a 160% increase over the fourth quarter of 2014 and 41% sequential growth from the third quarter of 2015. Net domestic product revenues for this product were $7.5 million for the year ended December 31, 2015, a 78% increase from 2014. Total HCV-related revenues, including exclusivity payments recognized under the HCV co-promotion agreement with AbbVie, were $7.4 million and $24.9 million for the fourth quarter and full-year of 2015, respectively, as compared to $5.1 million and $14.8 million for the fourth quarter and full-year of 2014, respectively.

- Consolidated net income for the fourth quarter of 2015 was $4.6 million, or $0.08 per share on a fully-diluted basis, which compares to a consolidated net loss of $2.7 million, or $0.05 per share, for the fourth quarter of 2014. Consolidated net income for the year ended December 31, 2015 was $8.2 million, or $0.14 per share on a fully-diluted basis, which compares to a consolidated net loss of $4.6 million, or $0.08 per share, for 2014. The Company's bottom line results for the full-year of 2014 included a $5.5 million payment received as a result of the termination of the Company's drug assay collaboration with Roche Diagnostics. This payment was recorded as an offset to expenses in the second quarter of 2014 and did not recur in 2015.
- Cash and short-term investments totaled $101.3 million and working capital amounted to $111.5 million at December 31, 2015.

"We are pleased with our fourth quarter and full-year 2015 performance," said Douglas A. Michels, President and CEO of OraSure Technologies. "Both our quarterly and annual revenues reached record levels. Our molecular collection systems and HCV product lines continue to be the primary growth drivers for our business and the strong fourth quarter finish creates a solid foundation as we start the new year."

Financial Results

Consolidated net product revenues for the fourth quarter and full-year of 2015 increased 13% and 6% over the comparable periods of 2014, respectively, primarily as a result of higher sales of the Company's molecular collection systems, OraQuick® HCV and Intercept® products. Higher sales of the Company's OraQuick® In-Home HIV test also contributed to the increase in current quarter revenues. These increases were partially offset by lower sales of the Company's OraQuick® professional HIV and cryosurgical systems products. In addition, net product revenues for the fourth quarter and full-year of 2015 included $1.0 million and $2.3 million, respectively, in sales of the Company's OraQuick® Ebola Rapid Antigen test. This test was not sold in 2014.

Consolidated other revenues for the fourth quarter and full-year of 2015 were $3.7 million and $15.3 million, respectively. Other revenues in the current quarter included $3.4 million of exclusivity payments recognized under the Company's HCV co-promotion agreement with AbbVie and $319,000 of Ebola-related funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority ("BARDA"). Other revenue in the full-year of 2015 included $13.5 million of AbbVie exclusivity payments and $1.8 million in BARDA funding. Other revenues in the fourth quarter and full-year of 2014 included $3.4 million and $7.6 million of AbbVie exclusivity payments, respectively.

Consolidated gross margin for the three months and year ended December 31, 2015 was 68% and 67%, respectively. Consolidated gross margin for both the three months and year ended December 31, 2014 was 63%. Gross margin for the current quarter increased largely due to a reduction in royalty expense and in scrap and spoilage costs. Gross margin for the full-year improved largely due to the $7.7 million increase in other revenues, a reduction in royalty expense, and a favorable change in the exchange rate between the Canadian and U.S. dollar. Other revenues contributed approximately 500 and 300 basis points to gross margin for the years ended December 31, 2015 and 2014, respectively. The full-year 2015 impact of the favorable change in exchange rate was approximately $800,000, as compared to approximately $400,000 in 2014.

Consolidated operating expenses decreased to $17.8 million during the fourth quarter of 2015 compared to $20.5 million in the comparable period of 2014. This decrease was largely due to lower costs associated with the AbbVie co-promotion agreement, lower research and development expenses, and a favorable change in the Canadian – U.S. dollar exchange rate.

For the year ended December 31, 2015, consolidated operating expenses were $72.2 million, an increase from the $71.4 million reported for the year ended December 31, 2014. This increase was largely due to the absence of the $5.5 million Roche termination payment received in 2014 which was treated as an expense reduction, higher legal costs, and increased costs associated with the AbbVie co-promotion agreement, partially offset by lower promotional expenses for the Company's OraQuick® In-Home HIV test and the impact of a favorable change in the Canadian – U.S. dollar exchange rate. Promotional expenses for the OraQuick® In-Home HIV test were $1.8 million and $8.5 million for the full-year of 2015 and 2014, respectively. The full-year 2015 impact of the favorable change in exchange rate was approximately $2.0 million, as compared to $900,000 in 2014.

The Company's cash and short-term investment balance totaled $101.3 million at December 31, 2015 compared to $97.9 million at December 31, 2014. Working capital was $111.5 million at December 31, 2015 compared to $104.8 million at December 31, 2014. For the year ended December 31, 2015, the Company generated $15.8 million in cash from operations.

First Quarter 2016 Outlook

The Company expects consolidated net revenues to range from $28.5 to $29.0 million and is projecting consolidated net income of between $0.01 and $0.02 per share.

Financial Data

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

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2015	2014	2015	2014
Results of Operations				
Net revenues	$32,382	$28,681	$119,719	$106,464
Cost of products sold	10,452	10,704	39,426	39,840
Gross profit	21,930	17,977	80,293	66,624
Operating expenses:				
Research and development	2,693	3,817	11,654	12,058
Sales and marketing	8,623	10,290	35,088	41,118
General and administrative	6,522	6,433	25,493	23,750
Gain on contract termination	—	—	—	(5,500)
Total operating expenses	17,838	20,540	72,235	71,426
Operating income (loss)	4,092	(2,563)	8,058	(4,802)
Other income	379	287	774	531
Income (loss) before income taxes	4,471	(2,276)	8,832	(4,271)
Income tax (benefit) expense	(145)	376	665	343
Net income (loss)	$ 4,616	$ (2,652)	$ 8,167	$ (4,614)
Earnings (loss) per share:				
Basic	$ 0.08	$ (0.05)	$ 0.14	$ (0.08)
Diluted	$ 0.08	$ (0.05)	$ 0.14	$ (0.08)
Weighted average shares:				
Basic	56,308	56,105	56,397	55,949
Diluted	56,678	56,105	56,846	55,949

Summary of Net Revenues by Market and Product (Unaudited)

Market	Three Months Ended December 31, Dollars 2015	Dollars 2014	% Change	Percentage of Total Net Revenues 2015	Percentage of Total Net Revenues 2014
Infectious disease testing	$14,546	$12,602	15%	45%	44%
Substance abuse testing	2,686	2,250	19	8	8
Cryosurgical systems	2,964	3,377	(12)	9	11
Molecular collection systems	7,775	6,255	24	24	22
Insurance risk assessment	695	800	(13)	2	3
Net product revenues	28,666	25,284	13	88	88
Other	3,716	3,397	9	12	12
Net revenues	$32,382	$28,681	13%	100%	100%

Market	Year Ended December 31, Dollars 2015	Dollars 2014	% Change	Percentage of Total Net Revenues 2015	Percentage of Total Net Revenues 2014
Infectious disease testing	$ 49,129	$ 47,515	3%	41%	45%
Substance abuse testing	10,271	8,437	22	8	8
Cryosurgical systems	11,920	15,505	(23)	10	15
Molecular collection systems	29,924	23,778	26	25	22
Insurance risk assessment	3,214	3,659	(12)	3	3
Net product revenues	104,458	98,894	6	87	93
Other	15,261	7,570	102	13	7
Net revenues	$119,719	$106,464	12%	100 %	100%

HIV Revenues	Three Months Ended December 31, 2015	2014	% Change	Year Ended December 31, 2015	2014	% Change
Domestic	$6,809	$ 8,363	(19)%	$24,956	$29,933	(17)%
International	415	587	(29)	2,410	2,483	(3)
Domestic OTC	2,069	1,502	38	6,992	6,493	8
Net product revenues	$9,293	$10,452	(11)%	$34,358	$38,909	(12)%

HCV Revenues	Three Months Ended December 31, 2015	2014	% Change	Year Ended December 31, 2015	2014	% Change
Domestic	$2,698	$1,036	160%	$ 7,502	$ 4,220	78%
International	1,306	707	85	3,884	3,048	27
Net product revenues	4,004	1,743	130	11,386	7,268	57
Amortization of exclusivity payments	3,397	3,397	—	13,479	7,570	78
Net HCV-related revenues	$7,401	$5,140	44%	$24,865	$14,838	68%

Intercept® Revenues	Three Months Ended December 31, 2015	2014	% Change	Year Ended December 31, 2015	2014	% Change
Net Intercept® revenues	$2,048	$1,629	26%	$7,813	$6,101	28%

Cryosurgical Systems Revenues	Three Months Ended December 31, 2015	2014	% Change	Year Ended December 31, 2015	2014	% Change
Domestic professional	$1,043	$2,149	(51)%	$ 4,311	$ 6,750	(36)%
International professional	157	111	41	916	693	32
Domestic over-the-counter	90	108	(17)	390	108	261
International over-the-counter	1,674	1,009	66	6,303	7,954	(21)
Net cryosurgical systems revenues	$2,964	$3,377	(12)%	$11,920	$15,505	(23)%

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2015	December 31, 2014
Assets		
Cash	$ 94,094	$ 92,867
Short-term investments	7,225	5,000
Accounts receivable, net	19,265	16,138
Inventories	13,242	15,763
Other current assets	2,888	1,446
Property and equipment, net	20,083	17,934
Intangible assets, net	12,591	17,505
Goodwill	18,250	21,734
Other non-current assets	1,683	1,246
Total assets	$ 189,321	$ 189,633
Liabilities and Stockholders' Equity		
Accounts payable	$ 5,087	$ 7,148
Deferred revenue	9,735	8,043
Other current liabilities	10,412	11,271
Other non-current liabilities	1,768	1,234
Deferred income taxes	2,883	3,236
Stockholders' equity	159,436	158,701
Total liabilities and stockholders' equity	$ 189,321	$ 189,633

Additional Financial Data (Unaudited)	Year ended December 31, 2015	2014
Capital expenditures	$ 3,744	$3,005
Depreciation and amortization	$ 5,696	$6,307
Stock-based compensation	$ 6,046	$5,744
Cash provided by operating activities	$15,773	$7,526

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2015 full-year and fourth quarter financial results, certain business developments and financial guidance for the first quarter of 2016, 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 #20249565 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 10, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #20249565.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of point-of-care diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its first-to-market, innovative products include rapid tests for the detection of antibodies to HIV and HCV on the OraQuick® platform, oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications, and oral fluid laboratory tests for detecting various drugs of abuse. 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, commercial and industrial entities and consumers. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

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 co-promotion agreement 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 DNAG 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; 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, 2014, 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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Exhibit 99.2

OraSure Technologies, Inc.

2015 Fourth Quarter and Full-Year

Analyst/Investor Conference Call

February 3, 2016

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

Thank you Rena. Good afternoon everyone and welcome to our call.

Our fourth quarter 2015 results exceeded expectations and contributed to a record performance for the full year.

- Consolidated net revenues of $32.4 million in Q4 exceeded our guidance for the quarter, driven by strong molecular collection systems and OraQuick® HCV sales.
- Molecular collection systems revenues increased 24% from the prior year quarter.
- HCV sales increased 130% over Q4 of 2014 and 39% sequentially from Q3. Total HCV-related revenues, which include exclusivity payments under our HCV co-promotion agreement with AbbVie, were $7.4 million for the fourth quarter.
- Strong revenue growth, combined with improved margins and lower operating expenses, generated $4.6 million in consolidated net income for the fourth quarter. This was the fourth consecutive quarter of profitable performance for the Company.
- All of this led to full-year 2015 consolidated net revenues of $119.7 million and consolidated net income of $8.2 million.

Later in the call I will provide additional highlights regarding our business. But before I do that, Ron will discuss our Q4 financial performance in greater detail and our expectations for the first quarter of 2016.

So with that, I will turn the call over to Ron.

Fourth Quarter 2015 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our fourth quarter 2015 consolidated net revenues increased 13% to $32.4 million, compared to $28.7 million reported in 2014. Our consolidated net product revenues of $28.7 million also increased 13%, largely as a result of higher sales of our OraQuick® HCV, molecular collection systems, OraQuick® Ebola, Intercept®, and OraQuick® In-Home HIV products, partially offset by lower sales of our OraQuick® HIV and cryosurgical systems products.

Other revenues were $3.7 million in the current quarter, of which $3.4 million represents the recognition of exclusivity payments under the AbbVie agreement and $319,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the fourth quarter of 2014 also included $3.4 million of AbbVie exclusivity payments.

HCV product revenues increased 130% to $4.0 million in Q4 from $1.7 million in the prior year. Domestic OraQuick® HCV product sales increased 160% in the fourth quarter of 2015 to $2.7 million from $1.0 million in the prior year period. This increase was primarily due to a large order of product purchased for deployment to the federal government as part of an HCV testing program. We also saw an expansion of our core domestic HCV revenues through the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International sales of our HCV test in the fourth quarter of 2015 increased 85% to $1.3 million from $707,000 in the same period last year, primarily due to the expansion of our HCV business in Asia and the timing of purchases by a multi-national humanitarian organization. Total HCV-related revenues, including the AbbVie exclusivity payments, increased 44% to $7.4 million in the fourth quarter of 2015 compared to $5.1 million in the fourth quarter of 2014.

In 2015, we began selling our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. Sales of this product contributed $1.0 million in product revenues during the fourth quarter of 2015.

Domestic sales of our professional HIV product decreased 19% to $6.8 million in the fourth quarter of 2015, compared to $8.4 million in the fourth quarter of 2014. This decrease was the result of customers continuing to move some of their testing to 4th generation automated HIV immunoassays or to competitive point-of-care HIV tests that are perceived to be more sensitive. We expect continued pressure on our professional HIV business.

Sales of our OraQuick® In-Home test rose 38% to $2.1 million in the current period from $1.5 million in the fourth quarter of 2014, largely due to an increase in sales volume in the period immediately following a celebrity's announcement that he had tested positive for the HIV virus, a price increase implemented last August and the timing of orders placed by our retail trade customers.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line in the genomics market, increased 24% to $7.8 million in the fourth quarter of 2015 compared to $6.3 million in the fourth quarter of 2014. Commercial sales increased 37% primarily as a result of higher sales into the personal genome service market, partially offset by a decline in sales to two other commercial customers. Sales to academic customers decreased 11%, largely due to customer ordering patterns.

Substance abuse testing revenues rose 19% to $2.7 million in the fourth quarter of 2015 compared to $2.3 million in 2014. This increase is largely due to higher sales of our Intercept® device into the workplace testing market.

Fourth quarter 2015 cryosurgical revenues decreased 12% to $3.0 million from $3.4 million in the fourth quarter of 2014. Domestic sales of our professional product decreased 51% to $1.0 million in the fourth quarter of 2015 compared to $2.1 million in

the fourth quarter of 2014 due to distributor consolidation, competition from new private-label brands, and a large purchase in the fourth quarter of 2014 by one our distributors that did not repeat in 2015. Sales of our OTC products in the international markets increased 66% to $1.7 million in the fourth quarter of 2015 compared to $1.0 million in the fourth quarter of 2014, primarily due to ordering patterns of our European distributor.

Gross Margin – Ron Spair

Gross margin for the fourth quarter of 2015 was 68% compared to 63% reported for the fourth quarter of 2014. Margin for the current quarter benefited from reductions in royalty expenses and scrap and spoilage costs.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the fourth quarter of 2015 were $17.8 million compared to $20.5 million in the comparable period of 2014. This decrease was the result of lower detailing costs associated with our HCV co-promotion agreement with AbbVie, lower research and development spending and a favorable change in the exchange rate between the Canadian and U.S. dollars.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $4.6 million, or $0.08 per share on a fully diluted basis, for the fourth quarter of 2015, compared to a net loss of $2.7 million, or $0.05 per share, for the same period of 2014.

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, 2015 was $101.3 million compared to $97.9 million at December 31, 2014. Cash generated by operating activities in the fourth quarter of 2015 was $667,000 compared to $858,000 million used in operating activities in the fourth quarter of 2014. During the fourth quarter of 2015, we used $4.9 million in cash to buy back stock under our previously authorized stock repurchase program.

First Quarter 2016 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the first quarter of 2016, we are projecting consolidated net revenues of approximately $28.5 to $29.0 million. We are also projecting consolidated net income of approximately $0.01 to $0.02 per share. Our expectations for Q1 include a $1.1 million order for OraQuick® HIV and HCV devices that had been received from a public health jurisdiction that normally orders at the end of their fiscal year. We had mentioned this order on the last call as potentially being realized in Q4 2015.

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

Business Update – Doug Michels

Thanks, Ron.

Molecular Collection Systems – Doug Michels

As noted earlier in the call, DNA Genotek continued the strong performance delivered in prior periods. Full-year revenues of $29.9 million increased 26% over 2014.

Genomics Market

As discussed previously, the bulk of our molecular collection systems revenues are generated in the genomics market, which consists of both academic research and commercial customers. Historically, these revenues have been split approximately 65% commercial and 35% academic research, and this pattern continued in 2015. Q4 revenue growth was driven almost entirely from sales into the U.S. commercial market.

The continued growth in the genomics market has been driven by sales to existing customers and an increasing amount of new opportunities. In fact, our business is developing a much more diversified base of accounts in this market, which we believe is very promising.

For example:

- In 2015, we were chosen to provide collection kits, custom packaging and fulfillment services for a large study on autism. The aim of this study is to build the largest genomic database for autism research in the world. Recruitment of participants for this study is expected to begin in 2016.
- We are also selling products to a personal genomics company providing services to the people of China. Our product line will be used to conduct genetic analysis of ancestral traits, health risks, disease screening, drug reactions, genetic characteristics and nutrition metabolism. We are excited about this opportunity and the chance to expand our business in this important marketplace.
- Finally, we are participating in a major longitudinal study on the epidemiology of aging, which has been collecting data since 2002 on adults aged 50 and over from nationally representative samples in several countries. Data collection has included a number of components and now a genetic component will be added through the use of our OraGene® kit.

These are just a few examples of some of the increasingly diverse revenue opportunities we are seeing in the genomics marketplace.

Microbiome Market

Another area of focus for our molecular collection business has been the microbiome market, through the offering of our OMNIgene™ ● Gut product. During 2015, we received CE mark approval and completed design validation on a high-throughput automated processing system for this product. Several technical manuscripts with academic and biotech groups are also in process which will report on the ability of this product to “snapshot” microbiome communities at the point of collection. We sold our collection kit to over 100 customers in 2015 and generated over $500,000 of revenue. Many of these customers were known to us through our genomics business and thus demonstrate the value of our broad brand recognition and pre-existing relationships.

In order to gain further insight into the microbiome market, we recently appointed Dr. Dan Knight as a scientific advisor to our DNA Genotek team. Dr. Knight is a

computational microbiologist and a leading authority in the application of machine learning to discovering linkages between microbiome, environment and human disease. He is an assistant professor at the University of Minnesota and received a Ph.D. from the University of Colorado with post-doctoral fellowships at M.I.T. and Harvard. We believe Dr. Knight's insight and assistance will be invaluable as we work to expand our microbiome product and service offerings.

We are excited about the microbiome market and, in fact, we see similarities to our genomics business, where there was initially a strong academic research opportunity early in the market's development followed by commercial applications as the market matures. We believe there is a significant long-term opportunity in the microbiome market.

Tuberculosis

A final market our team at DNA Genotek is pursuing falls under the infectious disease umbrella and is focused on tuberculosis. Products offered in this space include the OMNIgene™ ● Sputum and PrepIT™ MAX products. Healthcare providers from more than 60 countries have expressed interest in evaluating these products and more than 20 entities, ranging from Ministries of Health, non-government organizations, donor agencies and diagnostic test developers, have begun their evaluations of our product offerings.

A major milestone in 2015 was a collaboration among various organizations to support future World Health Organization endorsement of our tuberculosis products. Once secured, this endorsement will enable countries to procure our products with funding provided by the Global Fund and other international funding agencies. Our tuberculosis products are well positioned to support the National Action Plan for combatting multi drug-resistant tuberculosis, recently announced by the Obama Administration, by providing much needed solutions to developing countries that are at the highest risk for multi-drug resistant tuberculosis.

We are excited about the potential opportunities in this market, and we are realistic about the complexity involved in achieving commercial success. It will likely take some time for this opportunity to translate into meaningful financial results.

Infectious Disease Testing – Doug Michels

Turning more broadly to our core infectious disease testing business, revenues were up 15% compared to the fourth quarter of 2014. As Ron explained, strong growth in OraQuick® HCV sales more than offset declines in our domestic professional HIV business. Although the trends in our HIV business are likely to continue, we do see opportunities for growth, primarily in the international marketplace.

During the past several years, we have been working to develop a lower cost version of our HIV self-test for use in certain countries. We now have a working model that has the same robust diagnostic capabilities of our U.S. approved test. Specifically, we are working with Population Services International ("PSI"), a leading global health organization, along with UNITAID, the World Health Organization and health officials from Malawi, Zambia and Zimbabwe to launch the UNITAID- PSI HIV Self-Testing in Africa, or "STAR", project. As part of STAR, PSI is implementing a four-year pilot program funded by UNITAID which will utilize a self-test that we have specifically tailored for the African marketplace. The purpose of the STAR project is to generate crucial information about how best to deliver HIV self-testing, how to generate demand for HIV testing in this manner and what the potential public health impact of self-testing will be. Initial research indicates that the rates of people accepting a self-testing approach in Africa are much higher than traditional HIV testing programs. Our test was chosen for the PSI pilot because of its quality, ease-of-use and oral fluid option. We expect initial shipments to PSI during the first quarter of 2016.

As noted earlier, HCV sales for the quarter grew nicely, with total revenues up 130% from the fourth quarter of 2014. Q4 revenues were also up 39% sequentially from the third quarter of 2015. From a full-year perspective, our total HCV product revenues grew 57% compared to the prior year.

Our fourth quarter HCV sales reflect strong growth in both the domestic and international markets. Higher domestic sales were driven by expansion of existing testing programs,

new programs in the public health market, and new pilot initiatives in populations with high prevalence. As Ron mentioned, we also filled a large order that will be deployed for a federal government screening initiative. It is not clear whether purchases for this program will repeat in 2016. Internationally, we experienced higher sales in Asia and we received additional orders from the large multi-national healthcare organization we have been supplying product to in prior periods.

Turning briefly to our HIV In-Home Test, we are pleased with the performance of this product line, particularly its full-year contribution. Full-year sales increased 8% from 2014 and, more importantly, this brand generated a net profit contribution of $1.5 million for the year. Throughout 2015, we focused on developing programs for deployment in the public health market. At least one major public health customer has launched such a program and we expect continued revenues from this customer and possibly others in 2016.

Finally, we are pleased to see that our Ebola product contributed a total of $4.0 million in revenues in 2015, which includes BARDA funding and initial product sales to the CDC. More importantly, this product represents a crucial new diagnostic tool that the CDC is now using in West Africa in support of ongoing surveillance efforts. It is important to note that while great strides have been made to contain the Ebola epidemic, new cases continue to appear and, unfortunately, deaths continue to occur. There is an ongoing need for surveillance and as a result, we believe the role for an accurate, rapid point-of-care Ebola test is just as important as ever. We are working to expand the claims and related regulatory approvals for our Ebola test and will continue to seek sustainable and substantial product purchase commitments throughout 2016.

Conclusion

So in closing, 2015 was a great year for OraSure. Strong revenue growth, full-year profitability and continued improvement of our molecular collection systems and OraQuick® HCV businesses were the major highlights. We expect the momentum in these segments to continue. Opportunities for additional growth also exist in the

microbiome and tuberculosis markets and, possibly, for our rapid Ebola test. We will continue to build upon our success in 2015 by driving deeper penetration in our existing markets and execute on exciting new market opportunities in 2016. Thank you again for your continued interest in our work.

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 co-promotion agreement 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; 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,

2014, 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 call, and we undertake no duty to update these statements.