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 8, 2017

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 8, 2017, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter and full year ended December 31, 2016 and financial guidance for the first quarter of 2017. 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 8, 2017, 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, 2016, provided financial guidance for the first quarter of 2017 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 8, 2017, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31 2016 and financial guidance for the first quarter of 2017.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full-Year 2016 Analyst/ Investor Conference Call Held February 8, 2017.

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 8, 2017

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

Index to Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 8, 2017, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter and full year ended December 31 2016 and financial guidance for the first quarter of 2017.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Fourth Quarter and Full-Year 2016 Analyst/ Investor Conference Call Held February 8, 2017.

Exhibit 99.1

OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces 2016 Fourth Quarter and Full-Year Financial Results

BETHLEHEM, PA – February 8, 2017 – (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 fourth quarter and full year ended December 31, 2016.

Financial Highlights

- Consolidated net revenues for the fourth quarter of 2016 were $35.5 million, a 10% increase from the fourth quarter of 2015. Consolidated net revenues for the year ended December 31, 2016 rose to $128.2 million, a 7% improvement from 2015.
- Net molecular collection systems revenues were $8.6 million during the fourth quarter of 2016, which represents a 10% increase over the fourth quarter of 2015. Net molecular collection systems revenues for the year ended December 31, 2016 were $32.2 million, an 8% improvement from 2015.
- Net revenues from international sales of the Company's OraQuick® HIV products were $1.3 million for the fourth quarter of 2016, representing a 217% increase over the fourth quarter of 2015. Net international HIV revenues were $5.2 million for the year ended December 31, 2016, a 118% increase from 2015.
- International sales of the Company's OraQuick® HCV test were $2.9 million for the fourth quarter of 2016, representing a 123% increase from the fourth quarter of 2015. International HCV sales for the year ended December 31, 2016 rose to $6.6 million, a 71% improvement from 2015.

- During the fourth quarter of 2016, the Company made its first shipments of product, worth $1.9 million, under an $18 million supply contract with a foreign government, largely consisting of OraQuick® HCV tests.
- Consolidated net income for the fourth quarter of 2016 was $7.2 million, or $0.13 per share on a fully-diluted basis, which compares to consolidated net income of $4.6 million, or $0.08 per share on a fully-diluted basis, for the fourth quarter of 2015. Consolidated net income for the year ended December 31, 2016 was $19.7 million, or $0.35 per share on a fully-diluted basis, which compares to consolidated net income of $8.2 million, or $0.14 per share on a fully-diluted basis, for the comparable period of 2015.
- Cash and short-term investments totaled $120.9 million and working capital amounted to $139.1 million at December 31, 2016.

“Our fourth quarter financial results exceeded expectations on the top and bottom lines,” said Douglas A. Michels, President and CEO of OraSure Technologies. “A major contributor to growth during both the quarter and full-year period was our international business. Expanding international sales of our HIV self-test and HCV product is a critical component of OraSure’s global growth strategy.”

Financial Results

Consolidated net product revenues for the fourth quarter of 2016 approximated those of the same period in 2015, primarily as a result of higher international sales of OraQuick® HIV and HCV tests and higher sales of the Company’s molecular collection systems products, largely offset by lower domestic sales of the Company’s OraQuick® HIV and HCV products and lower OraQuick® Ebola sales.

Consolidated net product revenues for the full year of 2016 increased 2% over 2015, primarily as a result of higher international sales of the Company’s OraQuick® HCV and HIV tests, and higher sales of the Company’s molecular collection systems and cryosurgical systems products. These increases were partially offset by lower domestic sales of the Company’s OraQuick® HIV and Ebola products.

Consolidated other revenues for the fourth quarter and full year of 2016 were $6.9 million and $21.3 million, respectively. This compares to consolidated other revenues for the fourth quarter and full year of 2015 of $3.7 million and $15.3 million, respectively. Exclusivity revenues recognized under the Company’s HCV co-promotion agreement with AbbVie for the three months and year ended December 31, 2016 were $6.1 million and $18.9 million, respectively. AbbVie exclusivity revenues for the three months and year ended December 31, 2015 were $3.4 million and $13.5 million, respectively. Other revenues in the fourth quarter and full-year of 2016 also included $747,000 and $2.3 million, respectively, of funding received from the U.S. Biomedical Advanced Research Development Authority (“BARDA”). Other revenues for the fourth quarter and full year of 2015 included $319,000 and $1.8 million, respectively, in BARDA funding.

Consolidated gross margin for the three months and year ended December 31, 2016 was 67% and 69%, respectively. Consolidated gross margin for the three months and year ended December 31, 2015 was 68% and 67%, respectively. Gross margin for the current quarter decreased due to a less favorable product mix and severance costs associated with a corporate restructuring plan implemented by the Company during the fourth quarter, partially offset by higher other revenues and improved overhead absorption. Gross margin for the full year improved primarily due to the increase in other revenues.

Consolidated operating expenses decreased to $16.9 million during the fourth quarter of 2016 compared to $17.8 million in the fourth quarter of 2015. For the year ended December 31, 2016, consolidated operating expenses were $67.8 million, a reduction from the $72.2 million reported for the year ended December 31, 2015. The quarterly decrease was largely due to lower detailing costs associated with the AbbVie HCV co-promotion agreement, lower commission costs, a decrease in bad debt expense, and a reduction in research and development expenses recorded as a result of a payment received to settle a claim against one of the Company's raw material suppliers. These decreases were partially offset by the corporate restructuring severance costs, increased legal fees, and higher staffing-related costs. The decrease in the full-year period was largely due to lower detailing costs associated with the AbbVie HCV co-promotion agreement and reduced research and development expenses due to the supplier settlement, partially offset by higher legal fees, severance costs, consulting fees and staffing-related expenses.

The Company's cash and short-term investment balance totaled $120.9 million at December 31, 2016, compared to $101.3 million at December 31, 2015. Working capital was $139.1 million at December 31, 2016, compared to $111.5 million at December 31, 2015. For the year ended December 31, 2016, the Company generated $22.8 million in cash from operations.

First Quarter 2017 Outlook

The Company expects consolidated net revenues to range from $31.0 to $31.5 million and is projecting consolidated net income of $0.17 to $0.18 per share for the first quarter of 2017. This guidance reflects the absence of revenues and costs associated with the AbbVie HCV co-promotion agreement, which terminated at the end of 2016, and a lower gross margin contribution from the increasing amount of international sales expected in 2017. The quarterly guidance also includes the after-tax impact of a $12.5 million litigation settlement recently announced by the Company.

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

Unaudited

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
Results of Operations				
Net revenues	$35,499	$32,382	$128,198	$119,719
Cost of products sold	11,545	10,452	40,171	39,426
Gross profit	23,954	21,930	88,027	80,293
Operating expenses:				
Research and development	1,207	2,693	9,754	11,654
Sales and marketing	7,121	8,623	29,652	35,088
General and administrative	8,553	6,522	28,356	25,493
Total operating expenses	16,881	17,838	67,762	72,235
Operating income	7,073	4,092	20,265	8,058
Other income	92	379	58	774
Income before income taxes	7,165	4,471	20,323	8,832
Income tax (benefit) expense	(31)	(145)	603	665
Net income	$ 7,196	$ 4,616	$ 19,720	$ 8,167
Earnings per share:				
Basic	$ 0.13	$ 0.08	$ 0.35	$ 0.14
Diluted	$ 0.13	$ 0.08	$ 0.35	$ 0.14
Weighted average shares:				
Basic	55,811	56,308	55,615	56,397
Diluted	57,232	56,678	56,513	56,846

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$13,679	$14,546	(6)%	39%	45%
Risk assessment testing	3,322	3,381	(2)	9	10
Cryosurgical systems	3,071	2,964	4	9	9
Molecular collection systems	8,565	7,775	10	24	24
Net product revenues	28,637	28,666	(0)	81	88
Other	6,862	3,716	85	19	12
Net revenues	$35,499	$32,382	10%	100%	100%

	Year Ended December 31,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$ 48,408	$ 49,129	(1)%	38%	41%
Risk assessment testing	13,068	13,485	(3)	10	11
Cryosurgical systems	13,234	11,920	11	10	10
Molecular collection systems	32,214	29,924	8	25	25
Net product revenues	106,924	104,458	2	83	87
Other	21,274	15,261	39	17	13
Net revenues	$128,198	$119,719	7%	100%	100%

	Three Months Ended December 31,			Year Ended December 31,		
HIV Revenues	2016	2015	% Change	2016	2015	% Change
Domestic	$5,054	$6,809	(26)%	$21,499	$24,956	(14)%
International	1,314	415	217	5,248	2,410	118
Domestic OTC	1,747	2,069	(16)	6,320	6,992	(10)
Net product revenues	$8,115	$9,293	(13)%	$33,067	$34,358	(4)%

HCV Revenues	Three Months Ended December 31, 2016	2015	% Change	Year Ended December 31, 2016	2015	% Change
Domestic	$ 2,218	$2,698	(18)%	$ 7,436	$ 7,502	(1)%
International	2,908	1,306	123	6,630	3,884	71
Net product revenues	5,126	4,004	28	14,066	11,386	24
Amortization of exclusivity payments	6,114	3,397	80	18,951	13,479	41
Net HCV-related revenues	$11,240	$7,401	52%	$33,017	$24,865	33%

Cryosurgical Systems Revenues	Three Months Ended December 31, 2016	2015	% Change	Year Ended December 31, 2016	2015	% Change
Domestic professional	$1,389	$1,043	33%	$ 5,545	$ 4,311	29%
International professional	165	157	5	771	916	(16)
Domestic OTC	288	90	220	1,350	390	246
International OTC	1,229	1,674	(27)	5,568	6,303	(12)
Net cryosurgical systems revenues	$3,071	$2,964	4%	$13,234	$11,920	11%

Condensed Consolidated Balance Sheets (Unaudited)

	December 31, 2016	December 31, 2015
Assets		
Cash and cash equivalents	$ 109,790	$ 94,094
Short-term investments	11,160	7,225
Accounts receivable, net	19,827	19,265
Inventories	11,799	13,242
Other current assets	3,865	2,888
Property and equipment, net	20,033	20,083
Intangible assets, net	10,337	12,591
Goodwill	18,793	18,250
Other non-current assets	2,331	1,683
Total assets	$ 207,935	$ 189,321
Liabilities and Stockholders' Equity		
Accounts payable	$ 4,633	$ 5,087
Deferred revenue	1,388	9,735
Other current liabilities	11,314	10,412
Other non-current liabilities	2,304	1,768
Deferred income taxes	2,446	2,883
Stockholders' equity	185,850	159,436
Total liabilities and stockholders' equity	$ 207,935	$ 189,321

	Year ended December 31,	
Additional Financial Data (Unaudited)	**2016**	**2015**
Capital expenditures	$ 4,353	$ 3,744
Depreciation and amortization	$ 5,687	$ 5,696
Stock-based compensation	$ 6,062	$ 6,045
Cash provided by operating activities	$22,767	$15,773

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2016 fourth quarter financial results, certain business developments and financial guidance for the first quarter of 2017, 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 #49022171 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 15, 2017, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #49022171.

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; 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 the Company 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 levels 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 testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") and other agencies; 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 the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; 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, 2015, 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.

# # #

Exhibit 99.2

OraSure Technologies, Inc.

2016 Fourth Quarter and Full-Year

Analyst/Investor Conference Call

February 8, 2017

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.

I am pleased to report that the Company had a terrific fourth quarter. Our financial performance exceeded expectations and we delivered record revenues and earnings for both Q4 and the full year 2016. We also moved forward on all of our strategic initiatives which will be key to continuing our growth in 2017 and beyond. We presented our new strategy at our Analyst Day at the NASDAQ MarketSite in New York City in late November and I am very pleased with the progress we made this past quarter.

Later in today's call, we will provide an update on each of the key initiatives outlined at our Analyst Day, but before that, we will provide a detailed financial review of the quarter. We will also take your questions.

So with that, let me turn the call over to Ron for his review of our financials.

Fourth Quarter 2016 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our fourth quarter 2016 consolidated net revenues increased 10% to $35.5 million, compared to $32.4 million reported in Q4 2015. Our consolidated net product revenues of

$28.6 million approximated those of the prior year period. Higher international sales of our OraQuick® HIV and HCV products along with higher sales of our molecular collection systems products were largely offset by a decline in domestic sales of our OraQuick® HIV and HCV products and lower sales of our OraQuick® Ebola and In-Home HIV tests.

Other Revenues were $6.9 million in the current quarter, of which $6.1 million represents the recognition of exclusivity revenue under the AbbVie HCV co-promotion agreement and $747,000 represents funding we received from BARDA related to our rapid Ebola and Zika products. Other Revenues in the fourth quarter of 2015 included $3.4 million of exclusivity revenue from AbbVie and $319,000 of BARDA funding.

International sales of our HCV test in the fourth quarter of 2016 rose 123% to $2.9 million from $1.3 million in the same period of 2015, primarily due to the first shipments of product to a foreign government as well as the continued expansion of our business in Asia. Domestic OraQuick® HCV product sales decreased 18% in the fourth quarter of 2016 to $2.2 million from $2.7 million in the prior year period, primarily due to the inclusion in Q4 2015 of a $1.3 million order for a U.S. government HCV testing program which did not repeat in 2016. This was partially offset by an increase in both the number and size of direct orders placed by public health and other customers during the current quarter.

International sales of our HIV products increased 217% to $1.3 million in the fourth quarter of 2016, compared to $415,000 in the fourth quarter of 2015. This increase was due to higher sales in Africa, Asia, the Middle East, and Europe.

Domestic professional HIV sales decreased 26% to $5.1 million in the fourth quarter of 2016, compared to $6.8 million in the fourth quarter of 2015, as result of customer ordering patterns, competition from other products, and budget reductions.

In 2015, we began selling our OraQuick® Ebola 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. Similar sales in the fourth quarter of 2016 were $197,000. We believe Ebola sales in future periods are likely given ongoing international surveillance efforts.

Sales of our OraQuick® In-Home HIV test decreased 16% to $1.7 million in the fourth quarter of 2016, compared to $2.1 in the fourth quarter of 2015 due to lower retail sales volumes partially offset by higher direct sales into an OTC public health program.

Our molecular collection systems revenues rose 10% to $8.6 million in the fourth quarter of 2016 compared to $7.8 million in the fourth quarter of 2015. Academic sales increased 18% primarily as a result of additional product sales to support a study on autism which commenced in 2016. Sales of our Oragene® product to commercial customers increased 4%, largely due to product shipped to a new personal genomics customer.

Gross Margin – Ron Spair

Gross margin for the fourth quarter of 2016 was 67% compared to 68% reported for the fourth quarter of 2015. Margin for the current quarter decreased primarily due to an unfavorable product mix and the inclusion in cost of goods sold of severance costs related to our recent corporate restructuring, partially offset by higher AbbVie exclusivity revenues and improved overhead absorption as a result of increased manufacturing activities during the current quarter.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the fourth quarter of 2016 were $16.9 million compared to $17.8 million in the comparable period of 2015. This decrease was the result of lower costs associated with our HCV co-promotion agreement with AbbVie, lower commissions, a reduction in bad debt expense, and a decrease in research and development expenses due to a $1.4 million dispute settlement received from a supplier of raw materials. These decreases were partially offset by severance costs associated with our corporate restructuring, higher legal expenses and an increase in staffing-related costs.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $7.2 million, or $0.13 per share on a fully diluted basis, for the fourth quarter of 2016, compared to net income of $4.6 million, or $0.08 per share, for the same period of 2015.

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, 2016 was $120.9 million compared to $101.3 million at December 31, 2015. Cash generated by operating activities through the full year of 2016 was $22.8 million compared to $15.8 million in the same period of 2015.

First Quarter 2017 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the first quarter of 2017, we are projecting consolidated net revenues of approximately $31.0 million to $31.5 million. As you consider this, I think some context regarding the revenue growth inherent in this projection would be useful. When you look back at Q1 2016, we recorded total revenues of $29.1 million which included $3.4 million of exclusivity amortization. The remaining $25.7 million in this figure represents product revenues and BARDA funding. With the AbbVie revenues ending in 2016, our Q1 2017 guidance of $31.0 million – $31.5 million consists entirely of product and BARDA revenues and represents growth of 21% to 23% from the comparable revenues in Q1 2016.

We are also projecting consolidated net income of approximately $0.17 to $0.18 per share for Q1 of 2017. This guidance reflects the absence of both revenues and costs associated with the AbbVie HCV co-promotion agreement as well as a lower gross margin contribution expected from increasing international revenues during the period. This net income guidance also includes the after-tax impact of the Ancestry settlement announced earlier this week.

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

Business Update – Doug Michels

Thanks, Ron. During our Analyst Day, we described the focus of our long-term strategy as growing our business in two key areas, which we refer to as growth pillars. The first pillar is our infectious disease business which includes our HCV, HIV self-test, Ebola, Zika and TB programs. The second pillar is our molecular business which consists of our personal genomics and microbiome products.

Infectious Disease Testing – Doug Michels

Let me first comment on the infectious disease business.

HCV Elimination Programs

The strong growth we are realizing and expect in our international HCV business is attributable to country-wide or large-scale HCV elimination or testing programs. Last year, we entered into a supply contract with a foreign government for $18 million of both HCV and HIV products. The majority of this contract is for our OraQuick® HCV test to support a nation-wide HCV testing and treatment program. Initial shipments occurred in Q4 and will continue throughout 2017. This is the largest product supply contract in OraSure's history and we believe it is just the beginning for these types of opportunities.

At the Analyst Day, we indicated we are working with other countries that are initiating large scale HCV testing programs. As a result of these efforts, we recently received a large order for both HCV and HIV tests from one of those countries. Some initial smaller purchases were also made by another country, which is typical as a precursor to initiating a larger scale HCV testing program. The list of countries evaluating broad testing programs is growing and we believe that additional significant opportunities will emerge over time.

While our international HCV business has stolen the spotlight lately, we are equally optimistic about growth opportunities in the domestic market. We expect continued growth in HCV sales in the U.S., primarily due to increasing demand in the public health market and from government accounts, in addition to drug treatment and community health centers.

HIV Self Testing

A second growth driver for infectious disease is HIV self-testing. We have previously discussed our ongoing work with Population Services International, or PSI, in support of a pilot program known as the “Self Testing in Africa” or “STAR” project. This pilot is being funded by UNITAID and is designed to deploy approximately 750,000 OraQuick® HIV self-tests in Sub-Saharan Africa during the first phase. Continued sales under this program are expected in 2017. We recently received an additional order from PSI for approximately 350,000 tests, which we are preparing for shipment here in the first quarter.

Our HIV self-tests are now being successfully deployed in Malawi, Zambia and Zimbabwe. Field reports on the use of our tests continue to be positive and we believe our product is fully meeting the needs of the STAR project. We are also working with several countries outside of STAR that have initiated studies as a precursor to implementing community based HIV self-testing programs.

To ensure the long-term success and stability of our international HIV self-testing business, we are pursuing the prequalification of our product by the WHO. Our submission is under active review and we expect to receive feedback later this month. WHO prequalification will enable countries purchasing our test to access global funding sources such as the Global Fund, UNITAID and PEPFAR.

Emerging Diseases

Another infection disease growth driver is in the area of emerging diseases, where our two focus programs are Ebola and Zika.

Our OraQuick® Ebola test is being used in several West African countries as a part of ongoing surveillance efforts. We shipped a small quantity of product in Q4 and an

additional small order here in the first quarter. We have additional orders planned for later in 2017. Our product remains the only rapid Ebola test with indications of use for both live patients and cadavers. Our clinical work for this product remains on track for a 510(k) submission to the FDA in late 2017 or early 2018. Given the history of the Ebola epidemic, the sporadic cluster outbreaks in 2016 and the ongoing transportation and infrastructure improvements in Africa that facilitated the last outbreak, we believe it is unlikely that we have seen the last of Ebola. We expect our product will be an important global health tool in the future.

With respect to Zika, our efforts to optimize our test are progressing. We remain on track to submit for Emergency Use Authorization, or EUA, from the FDA as early as Q2 of this year. We are committed to expediting the required optimization and clinical work wherever possible. Active Zika virus transmission continues in Central and South America, with sporadic cases of travel-related transmission still being reported in Florida. We anticipate that outbreaks similar to those experienced in the U.S. in 2016, particularly in Florida, Texas, Hawaii, California and other states and territories, will likely occur in 2017.

Tuberculosis

A final growth driver for the infectious disease business is our tuberculosis product. The clinical studies being performed by the Foundation for Innovative New Diagnostics, or FIND, in support of WHO endorsement of our OMNIgene®•Sputum product were completed in December. FIND has indicated they expect to issue a final data dossier to the WHO by the end of February. The WHO has indicated that it will review the FIND data and issue a broader review of all commercial sputum transport reagents later this year. As you know, WHO endorsement is critical to enable future customers to access global funding sources for product purchase.

We also continue to make progress on commercializing this product while pursuing WHO endorsement. DNA Genotek is negotiating with two foreign Ministries of Health in countries with high TB prevalence for the deployment of our OMNIgene®•Sputum on a national scale.

In addition, a major and successful evaluation funded by USAID was completed in late 2016 and the results were presented to another Health Ministry, USAID and several surrounding countries to inform national testing laboratories on the routine use of OMNIgene®•Sputum. Discussions with these countries and USAID are continuing.

Finally, a National Tuberculosis and Leprosy Control Program in Africa has begun planning a nation-wide pilot of OMNIgene®•Sputum as a follow-up to a prior laboratory assessment which singled out sputum transport as a major area for improvement. As you can see, there is a lot of activity occurring with respect to tuberculosis and we remain very optimistic about the prospects for this part of our business.

Molecular Business Growth Drivers – Doug Michels

Turning to our molecular growth pillar, there are two primary drivers – our genomics business and the microbiome market.

Genomics

During the fourth quarter, there were several developments in our genomics business, some of which we previewed at the Analyst Day.

- As you know, we announced a new contract with Helix for the supply of ORAgene®•Dx collection devices and our GenoFIND fulfillment services. We are not sure if investors fully appreciate the potential for this opportunity, so let me elaborate. We started providing kits and services in connection with Helix's official launch of its consumer genetic information service in November, and we expect sales to ramp in 2017. We are very excited about this new relationship and expect Helix to be a strong contributor in 2017 and beyond. Just based on public information about Helix and its business model, we think sales will likely grow substantially over time. As new partners are added to its service offerings menu, there is a greater chance Helix will attract new consumers not already in its database. This is where OraSure benefits as all those new consumers will require a DNA collection device. So as Helix grows so does the growth opportunity for OraSure.

- During the fourth quarter, we added a significant number of new commercial accounts, most of which are providers of diagnostic tests. Our commercial customers provide a more predictable revenue stream than academic accounts, which generally purchase based on grant funding cycles. The addition of these new accounts will continue to diversify our revenues and reduce customer concentration over time.
- Our business in China showed a strong increase in the fourth quarter, and we are still in the early stages of penetrating this market. We are now seeing repeat orders from multiple customers. In addition, as you may have seen, DNA Genotek recently announced a new multi-year supply agreement with WeGene, a company offering genetic testing and personalized healthcare services in Asia. We expect to start shipping against this contract in the second quarter and we are very excited about this new market and its large potential.
- There were also several new contracts obtained from academic customers. We were awarded a contract with a major bio bank in Europe for collecting samples from youths. We were also awarded a multi-year contract to provide kits for a large-scale research study in neuropsychiatric disorders in African populations. We are pleased to see these types of new academic opportunities.

Microbiome

Our microbiome business also continues to develop nicely. The number of microbiome kits sold in Q4 increased by 47% over Q3 and 91% over Q4 of 2015. We expect our microbiome business to double in 2017 from the roughly $1.1 million in revenues recorded in 2016.

The majority of our revenues have been derived from our gut or stool sample collection kits and related services with a smaller percentage derived from kits for other sample types. Academic customers continue to provide the vast majority of our microbiome sales, although the proportion of sales to commercial customers is growing. We are acquiring new commercial customers across several market segments, including direct-to-consumer firms, clinical stage biotechs and pharmaceutical companies that utilize both

our kits and the related order fulfillment, wet lab and analytical services we offer. Academic and clinical research scientists are also demonstrating a continued need for standardization in their case control and longitudinal studies with both segments generating repeat business for both kits and our microbiome services.

Operations Update – Doug Michels

A final area I want to discuss is the significant work in our Operations Department to meet the increasing demand for our diagnostic products.

As discussed on the last call, our second automated production line for the assembly of OraQuick® products has been delivered and installed and is now being validated. This equipment will supplement our current automated and manual production lines. The second line will be capable of producing all OraQuick® platform products and will initially manufacture our HIV and HCV products. When fully operational in mid-2017, the equipment will be able to produce approximately 8.0 million additional devices per year.

Because of the substantial growth projected in international markets where pricing is sometimes lower, we have initiated an effort to evaluate our global manufacturing. We have hired a very capable, well-known consulting firm to help us optimize the global footprint for the manufacture of our products that will align with our projections in international markets, minimize our cost of goods and logistics expenses, and maintain the highest levels of product quality and customer service. This effort is well under way and we expect completion sometime in the middle of this year. After potential strategies are identified and evaluated, we will make final decisions and begin implementation.

Conclusion

So, in summary, it was a highly productive end to 2016. We delivered a strong financial performance in the fourth quarter and advanced our key strategic objectives. Our international HIV and HCV products and our molecular collection systems business continue to fuel strong growth for OraSure. We believe the recent trends in these businesses will continue and will provide for solid growth in 2017.

If you missed our Analyst Day, I would like to emphasize the key take away from that day – that OraSure is in the very early stages of multiple large market opportunities. Through product innovation and the development of additional ways for customers to use our products, the door has opened to several new and large market opportunities that did not exist for us even a few years ago. We are very excited about OraSure's prospects and we believe we are well positioned to capitalize on those opportunities. These are definitely exciting times for the Company.

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; 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 the Company 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 levels 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 testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") and other agencies; 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 the Company's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to meet financial covenants in credit agreements; 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 our Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2015, 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.