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): November 2, 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** **(Address of Principal Executive Offices)**	**18015-1360** **(Zip Code)**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 – Results of Operations and Financial Condition.

On November 2, 2016, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended September 30, 2016, and providing financial guidance for the fourth 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 7.01 – Regulation FD Disclosure.

On November 2, 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 ended September 30, 2016, provided financial guidance for the fourth 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 November 2, 2016, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended September 30, 2016, and providing financial guidance for the fourth quarter of 2016.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Third Quarter 2016 Analyst/ Investor Conference Call Held November 2, 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: November 2, 2016

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

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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Chief Financial Officer
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OraSure Announces 2016 Third Quarter Financial Results

BETHLEHEM, PA – November 2, 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 three and nine months ended September 30, 2016.

Financial Highlights

- Consolidated net revenues for the third quarter of 2016 were $32.3 million, an 8% increase from the third quarter of 2015. Consolidated net revenues for the nine months ended September 30, 2016 were $92.7 million, a 6% increase from the comparable period of 2015.
- Net revenues from international sales of the Company's OraQuick® HIV test were $1.1 million for the third quarter of 2016, representing a 147% increase over the third quarter of 2015. Net international revenues for the OraQuick® HIV test were $3.9 million for the nine months ended September 30, 2016, a 97% increase from the comparable period of 2015.
- Net molecular collection systems revenues were $8.3 million during the third quarter of 2016, which represents a 14% increase over the third quarter of 2015. Net molecular collection systems revenues for the nine months ended September 30, 2016 were $23.6 million, a 7% increase from the comparable period in 2015.
- International sales of the Company's OraQuick® rapid HCV test were $1.3 million for the third quarter of 2016, representing a 35% increase from the third quarter of 2015. International sales of the HCV test for the nine months ended September 30, 2016 were $3.7 million, an increase of 44% from the comparable period of 2015.

- During the third quarter, the Company was awarded a contract for up to $16.6 million in total funding 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") related to the development of a rapid Zika test.
- The Company secured a contract with a foreign government to supply $18 million in diagnostic products, largely consisting of OraQuick® rapid HCV tests. The first shipment of this product is expected to occur in the fourth quarter of 2016 pending completion of certain ancillary documents required under the contract.
- Consolidated net income for the third quarter of 2016 was $6.2 million, or $0.11 per share on a fully-diluted basis, which compares to consolidated net income of $1.5 million, or $0.03 per share on a fully-diluted basis, for the third quarter of 2015. Consolidated net income for the nine months ended September 30, 2016 was $12.5 million, or $0.22 per share on a fully-diluted basis, which compares to consolidated net income of $3.6 million, or $0.06 per share, for the comparable period of 2015.
- Cash and short-term investments totaled $121.2 million and working capital amounted to $128.8 million at September 30, 2016.

"We are very pleased with the Company's financial performance for the third quarter, especially our strong bottom line results," said Douglas A. Michels, President and CEO of OraSure Technologies. "We continue to build on numerous international opportunities and have executed an $18 million product supply agreement with a foreign government in support of a country-wide HCV elimination program. Our molecular business continues to generate impressive growth and we were successful in obtaining government funding for continued work on our rapid Zika test. We believe the progress we have made on these key objectives has positioned us well for future success."

Financial Results

Consolidated net product revenues for the third quarter of 2016 decreased 1% from the comparable period of 2015 primarily as a result of the absence of sales of the Company's OraQuick® Ebola rapid antigen test, lower domestic sales of the Company's OraQuick® HIV and HCV products, and lower sales of the Company's cryosurgical systems and risk assessment products. These lower sales were partially offset by higher sales of the Company's molecular collection systems products and increased international OraQuick® HIV and HCV product sales.

Consolidated net product revenues for the first nine months of 2016 increased 3% over the comparable periods of 2015, primarily as a result of higher international sales of the Company's OraQuick® HCV and HIV products, 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 products, lower sales of the Company’s risk assessment products, and the absence of sales of the Company’s OraQuick® Ebola Rapid Antigen test in the current nine-month period.

Consolidated other revenues for the third quarter and first nine months of 2016 were $6.8 million and $14.4 million, respectively. This compares to consolidated other revenues for the third quarter and first nine months of 2015 of $4.1 million and $11.5 million, respectively. Exclusivity revenues recognized under the Company’s HCV co-promotion agreement with AbbVie for the three and nine month periods ended September 30, 2016 were $6.1 million and $12.8 million, respectively. AbbVie exclusivity revenues for the three and nine month periods ended September 30, 2015 were $3.4 million and $10.0 million, respectively. Other revenues in the third quarter and first nine months of 2016 also included $677,000 and $1.6 million, respectively, of funding received from BARDA. Other revenues for the third quarter and first nine months of 2015 included $750,000 and $1.5 million, respectively, in BARDA funding.

Consolidated gross margin for the three and nine months ended September 30, 2016 was 70% and 69%, respectively. Consolidated gross margin for the three and nine months ended September 30, 2015 was 69% and 67%, respectively. Gross margin for the current quarter increased primarily due to higher other revenues partially offset by a less favorable product mix. Gross margin for the nine-month period increased largely due to lower scrap and spoilage costs and the increase in other revenues, partially offset by an unfavorable product mix.

Consolidated operating expenses decreased to $16.5 million during the third quarter of 2016 compared to $19.1 million in the third quarter of 2015. For the nine months ended September 30, 2016, consolidated operating expenses were $50.9 million, a decrease from the $54.4 million reported for the nine months ended September 30, 2015. The quarterly decrease was largely due to lower costs associated with the AbbVie HCV co-promotion agreement partially offset by increased research and development expenses. The decrease in the nine-month period was largely due to lower costs associated with the AbbVie co-promotion agreement and lower research and development expenses, partially offset by increased general and administrative expenses.

The Company’s cash and short-term investment balance totaled $121.2 million at September 30, 2016 compared to $101.3 million at December 31, 2015. Working capital was $128.8 million at September 30, 2016 compared to $111.5 million at December 31, 2015. For the nine months ended September 30, 2016, the Company generated $23.4 million in cash from operations.

Fourth Quarter 2016 Outlook

The Company expects consolidated net revenues to range from $34.50 to $35.25 million and is projecting consolidated net income of $0.05 to $0.06 per share for the fourth quarter of 2016. This revenue guidance includes initial contributions from the new $18 million foreign government HCV product supply contract. However, OraSure will not commence shipment of product until certain additional ancillary documents required under the contract are completed. In addition, projected fourth quarter 2016 expenses will include $1.4 million in restructuring charges, consisting largely of work-force reduction costs which include severance and benefit expenses. Annual cost savings resulting from this restructuring as well as the termination of the Company's HCV co-promotion agreement with AbbVie at year end are expected to be $3.6 million, beginning in 2017.

Financial Data

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

Unaudited

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Results of Operations				
Net revenues	$32,251	$29,861	$92,699	$87,337
Cost of products sold	9,576	9,192	28,626	28,974
Gross profit	22,675	20,669	64,073	58,363
Operating expenses:				
Research and development	3,196	2,525	8,547	8,961
Sales and marketing	6,428	9,677	22,531	26,465
General and administrative	6,907	6,931	19,803	18,971
Total operating expenses	16,531	19,133	50,881	54,397
Operating income	6,144	1,536	13,192	3,966
Other income (expense)	498	81	(34)	395
Income before income taxes	6,642	1,617	13,158	4,361
Income tax expense	400	147	634	810
Net income	$ 6,242	$ 1,470	$12,524	$ 3,551
Earnings per share:				
Basic	$ 0.11	$ 0.03	$ 0.23	$ 0.06
Diluted	$ 0.11	$ 0.03	$ 0.22	$ 0.06
Weighted average shares:				
Basic	55,653	56,482	55,549	56,427
Diluted	56,524	56,692	56,271	56,900

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$10,412	$11,297	(8)%	32%	38%
Risk assessment testing	3,481	3,630	(4)	11	12
Cryosurgical systems	3,240	3,458	(6)	10	11
Molecular collection systems	8,327	7,329	14	26	25
Net product revenues	25,460	25,714	(1)	79	86
Other	6,791	4,147	64	21	14
Net revenues	$32,251	$29,861	8%	100%	100%

	Nine Months Ended September 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$34,729	$34,585	0%	37%	40%
Risk assessment testing	9,746	10,103	(4)	10	12
Cryosurgical systems	10,162	8,956	13	11	10
Molecular collection systems	23,649	22,148	7	26	25
Net product revenues	78,286	75,792	3	84	87
Other	14,413	11,545	25	16	13
Net revenues	$92,699	$87,337	6%	100%	100%

	Three Months Ended September 30,			Nine Months Ended September 30,		
HIV Revenues	2016	2015	% Change	2016	2015	% Change
Domestic	$4,858	$5,548	(12)%	$16,446	$18,147	(9)%
International	1,110	450	147	3,934	1,995	97
Domestic OTC	1,311	1,642	(20)	4,574	4,923	(7)
Net product revenues	$7,279	$7,640	(5)%	$24,954	$25,065	0%

HCV Revenues	Three Months Ended September 30, 2016	2015	% Change	Nine Months Ended September 30, 2016	2015	% Change
Domestic	$1,529	$1,914	(20)%	$ 5,218	$ 4,803	9%
International	1,293	957	35	3,722	2,577	44
Net product revenues	2,822	2,871	(2)	8,940	7,380	21
Amortization of exclusivity payments	6,114	3,397	80	12,837	10,081	27
Net HCV-related revenues	$8,936	$6,268	43%	$21,777	$17,461	25%

Cryosurgical Systems Revenues	Three Months Ended September 30, 2016	2015	% Change	Nine Months Ended September 30, 2016	2015	% Change
Domestic professional	$1,456	$1,600	(9)%	$ 4,155	$ 3,268	27%
International professional	162	258	(37)	607	757	(20)
Domestic OTC	339	137	147	1,062	300	254
International OTC	1,283	1,463	(12)	4,338	4,631	(6)
Net cryosurgical systems revenues	$3,240	$3,458	(6)%	$10,162	$ 8,956	13%

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Cash and cash equivalents	$ 113,536	$ 94,094
Short-term investments	7,618	7,225
Accounts receivable, net	15,471	19,265
Inventories	12,070	13,242
Other current assets	2,024	2,888
Property and equipment, net	20,069	20,083
Intangible assets, net	11,205	12,591
Goodwill	19,243	18,250
Other non-current assets	2,322	1,683
Total assets	$ 203,558	$ 189,321
Liabilities and Stockholders' Equity		
Accounts payable	$ 4,422	$ 5,087
Deferred revenue	7,911	9,735
Other current liabilities	9,618	10,412
Other non-current liabilities	2,289	1,768
Deferred income taxes	2,836	2,883
Stockholders' equity	176,482	159,436
Total liabilities and stockholders' equity	$ 203,558	$ 189,321

Additional Financial Data (Unaudited)	Nine months ended September 30, 2016	2015
Capital expenditures	$ 3,512	$ 1,885
Depreciation and amortization	$ 4,212	$ 4,259
Stock-based compensation	$ 4,438	$ 4,543
Cash provided by operating activities	$23,370	$15,105

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2016 third quarter financial results, certain business developments and financial guidance for the fourth 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 #85854320 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 November 9, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #85854320.

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 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 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") or 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 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 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.

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Exhibit 99.2

OraSure Technologies, Inc.

2016 Third Quarter

Analyst/Investor Conference Call

November 2, 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.

We are pleased to report solid financial performance on both the top and bottom lines for the third quarter of 2016.

- Consolidated net revenues for Q3 were $32.3 million, an 8% increase from Q3 2015. This increase resulted primarily from higher international and molecular collection systems sales and higher exclusivity revenues under our HCV co-promotion agreement with AbbVie.
- International HIV sales, driven primarily by increased demand in Africa, rose 147% from Q3 of 2015. International sales of our OraQuick® HCV test increased 35% compared to last year.
- Molecular collection systems revenues rose 14% from the prior year quarter, continuing the strong growth trend for this part of the business.
- We exceeded our bottom line guidance with $6.2 million in consolidated net income for the third quarter. This represents a $4.8 million improvement from the year-ago quarter.

Later in the call, I will provide some business updates, but before I do that, Ron will review our Q3 financial performance in more detail and provide our guidance for Q4.

So with that, let me turn the call over to Ron.

Third Quarter 2016 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our third quarter 2016 consolidated net revenues increased 8% to $32.3 million, compared to $29.9 million reported in 2015. Our consolidated net product revenues of $25.5 million decreased 1%, largely as a result of the absence of sales of our OraQuick® Ebola product, lower domestic sales of our OraQuick® HIV and OraQuick® HCV products, and lower sales of our cryosurgical systems and risk assessment products. These declines were almost entirely offset by higher sales of our molecular collection systems products and increased international sales of our OraQuick® HIV and OraQuick® HCV products during the current quarter.

Other revenues were $6.8 million in the current quarter, of which $6.1 million represents the recognition of exclusivity revenue under the AbbVie HCV co-promotion agreement and $677,000 represents funding we received from BARDA related to our rapid Ebola and Zika products. Other revenues in the third quarter of 2015 included $3.4 million of exclusivity revenue from the AbbVie agreement and $750,000 of BARDA funding.

International sales of our HCV test in the third quarter of 2016 rose 35% to $1.3 million from $957,000 in the same period last year, primarily due to the expansion of our business in Asia, higher sales to a multi-national humanitarian organization, and a new testing program in Africa. Domestic OraQuick® HCV product sales decreased 20% in the third quarter of 2016 to $1.5 million from $1.9 million in the prior year period due to customer ordering patterns and a reduction in funding of certain testing projects.

International sales of our professional HIV product increased 147% to $1.1 million in the third quarter of 2016, compared to $450,000 in the third quarter of 2015. This increase was due to higher sales in Africa and reflects the timing of orders placed and the start of a new

testing program. Domestic sales of our professional HIV product decreased 12% to $4.9 million in the third quarter of 2016, compared to $5.5 million in the third quarter of 2015, as result of customer ordering patterns and competition from other products.

In 2015, we began selling our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. Sales of this product contributed $482,000 in product revenues during the third quarter of 2015. We did not have similar sales in the third quarter of 2016. We believe Ebola sales in future periods are likely given ongoing international surveillance efforts.

Our molecular collection systems revenues rose 14% to $8.3 million in the third quarter of 2016 compared to $7.3 million in the third quarter of 2015. Sales of our Oragene® product to commercial customers increased 22%, largely due to the ordering patterns of one of our larger U.S. customers. Academic sales decreased 12% primarily as a result of the timing of orders placed by existing customers, partially offset by additional product sales to support a study on autism which commenced in 2016.

Gross Margin – Ron Spair

Gross margin for the third quarter of 2016 was 70% compared to 69% reported for the third quarter of 2015. Margin for the current quarter improved primarily due to higher AbbVie exclusivity revenues partially offset by a less favorable product mix.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the third quarter of 2016 were $16.5 million compared to $19.1 million in the comparable period of 2015. This decrease was the result of lower costs associated with our HCV co-promotion agreement with AbbVie, partially offset by increased research and development expenses.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $6.2 million, or $0.11 per share on a fully diluted basis, for the third quarter of 2016, compared to net income of $1.5 million, or $0.03 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 September 30, 2016 was $121.2 million compared to $101.3 million at December 31, 2015. Cash generated by operating activities through the first nine months of 2016 was $23.4 million compared to $15.1 million in same period of 2015.

Fourth Quarter 2016 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the fourth quarter of 2016, we are projecting consolidated net revenues of approximately $34.5 million to $35.25 million. It should be noted that this revenue projection includes approximately $1.6 million in sales to a foreign government primarily for a country-wide HCV elimination program. Although the main purchase contract has been executed, we will not ship product until certain ancillary documentation is received from the purchasing country.

We are also projecting consolidated net income of approximately $0.05 to $0.06 per share. Our bottom line results for Q4 are projected to be lower than those from the fourth quarter of 2015 for several reasons. Q4 2015 domestic HCV revenues included a large order of product purchased for deployment to the federal government as part of an HCV testing program. Purchases for this program are not expected to repeat in 2016. In addition, Q4 2016 results will include $1.4 million in restructuring charges consisting largely of severance and benefit expenses. Cost savings relating to this restructuring as well as the termination of our co-promotion agreement with AbbVie are expected to result in approximately $3.6 million of annual savings, beginning in 2017. Barring any major change to our business model, we expect to see a meaningful drop in our expense run rate starting in 2017.

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

Business Update – Doug Michels

Thanks, Ron.

Infectious Disease Testing – Doug Michels

Let me turn first to our infectious disease testing business. The primary take away is that the trends seen in recent quarters are continuing with continued strong growth in our international business, largely offsetting declines in the domestic markets.

HIV Business

Increasing international sales is an important strategic priority for our Company. The largest contribution in this area during the third quarter came from sales of our professional OraQuick® HIV test, particularly in Africa.

As indicated in prior calls, we believe a significant growth driver will be HIV self-testing in Africa and other developing countries. Today, the primary purchaser of our HIV self-tests is Population Services International ("PSI"), a leading global health organization, which has launched the Self-Testing in Africa or "STAR" project in collaboration with UNITAID, the World Health Organization ("WHO") and health officials from Malawi, Zambia and Zimbabwe. Phase I of this program is designed to deploy approximately 750,000 OraQuick® HIV self-tests that we designed specifically for developing markets.

Our tests are now being successfully deployed by PSI and our understanding is that self-testing has been well received and is providing a means for individuals to know their HIV status who have never been tested before. PSI generally orders in large quantities and then deploys the tests over a several month period. As a result, there were no PSI purchases during the third quarter. However, we expect an additional PSI order to be placed in Q4 with scheduled delivery during Q1 of 2017.

As previously noted, we are aggressively pursuing prequalification of our HIV self-test by the WHO. I am happy to report that our prequalification submission was completed and

filed in September and our submission is under review by the WHO. This prequalification is critical for our customers to obtain sustainable funding from such international sources as the Global Fund, USAID and PEPFAR.

Since the STAR project was launched, several additional countries have initiated pilot studies as a precursor to deploying our HIV self-test. We remain optimistic about the prospects for HIV self-testing internationally and believe it will be a significant future growth driver in our infectious disease testing business.

HCV Business

Turning to HCV, our total product revenues for the third quarter were essentially flat, as a result of a combination of lower domestic sales and strong growth in international markets. The decline in domestic revenues was largely a timing issue, driven primarily by purchasing patterns in the public health market. Those of you who have followed us for some time likely understand that the procurement process for public health entities can be somewhat unpredictable with orders shifting from period to period due to funding and other matters.

The quarterly decline in domestic HCV revenues was largely off-set by the international growth. As Ron explained, the increase internationally was driven by demand both in Asia and from a large international NGO that is an existing customer. As with our HIV business, increasing international HCV sales is a strategic priority and we expect continued growth from these markets in future periods.

Overall, our HCV franchise remains strong and we expect total HCV sales to continue to grow on both a year-over-year and quarter-to-quarter basis going forward. Our confidence is supported by a number of ongoing initiatives.

- As mentioned during our last call, we recently executed the largest new supply contract for rapid tests in our Company’s history. The contract calls for us to supply a foreign government with $18 million of product, the vast majority of

which is our OraQuick® HCV test. The product is being purchased in support of a country-wide HCV elimination initiative. We have not yet begun shipping product under this contract because certain ancillary documents still need to be completed. Some of these documents have been finalized, but some have not and we understand this is due to workload issues with the purchaser. Our expectation is that all ancillary documents will be completed in Q4 and that shipments will begin yet this year. Additional guidance on the financial impact of this contract will be provided once the required ancillary documents are completed.

- We believe this contract will lead to other international opportunities. We recently shipped HCV tests to another country in support of a pilot program, which may lead to a large scale HCV screening program. We will keep you posted as these other opportunities develop.
- On the domestic front, the Southern Cities Initiative mentioned on our last call is under way with several sites now actively testing individuals. Reports from the field indicate this initiative is going well with initial data from one of the sites indicating HCV prevalence rates in excess of 4%. As you may recall, this initiative was announced by the National Black Leadership Commission on AIDS and is being supported by several industry partners, including OraSure and Gilead Sciences.
- We are also working with an industry partner to bring HCV test and treat programs into drug treatment centers. These centers generally serve populations with a high prevalence of HCV infection and are looking to provide comprehensive services to their patients. Based on some initial work, the pilot drug treatment center for this initiative has decided to screen its patients on an ongoing basis. We expect to start shipments of HCV tests to approximately 60 of this entity’s nationwide centers by the end of the year. Additionally, our industry partner is in discussions with several additional drug treatment centers across the nation.
- Another initiative we have implemented is a program designed to assist organizations who may be interested in starting new HCV testing programs. In

many cases, these types of organizations need to assess the effectiveness of our product and likely success of a possible screening program in order to obtain funding. This program is being offered to assist with the evaluation process. We have received over 170 applications and we expect to begin implementing the program before the end of this year.

Emerging Diseases

Another recent strategic priority has been our focus on addressing emerging infectious diseases that have a global public health impact.

As you know, the first product developed in this area is our rapid Ebola test. We are continuing to supply this product to the CDC under an Emergency Use Authorization ("EUA") granted by the FDA, for ongoing surveillance activities primarily in West Africa. We expect another shipment to the CDC sometime in the fourth quarter. Our rapid Ebola test is still the only device approved for use on both live patients and cadavers. In the meantime, we are making good progress in preparing to submit this product for FDA 510(k) clearance and expect to enter the validation stage of that work shortly.

We are also continuing our work to develop an OraQuick® rapid Zika test. During the third quarter, we executed a funding contract with BARDA for the continued optimization of this product and clinical activities related to both EUA and 510(k) approvals. The current device we have developed is showing strong sensitivity and specificity and we are continuing to optimize the design to ensure appropriate performance for the multiple markets we expect to serve with this test. We continue to receive encouragement from both regulatory agencies and many potential customers on the need for our rapid test and we will keep you informed as we make additional progress on this important new product.

Our success with both the OraQuick® Ebola and Zika products further confirms our view that our OraQuick® technology provides a strong and versatile testing platform. We intend to build on our reputation as a reliable and preferred source of diagnostic solutions for emerging diseases globally and look for new opportunities to build out this part of our business.

Molecular Collection Systems – Doug Michels

Turning now to molecular collections, the solid revenue growth reported for Q3 was driven primarily by performance in the commercial market. This growth is particularly noteworthy when you consider that our Q3 2015 revenue included approximately $1 million in revenue from two commercial customers who subsequently filed for bankruptcy and have thus not reordered product. The commercial growth was partially off-set by somewhat lower revenues in the academic market.

Genomics

Our genomics business continues to perform very well, with more than 10 new commercial accounts added in Q3. Although some of these new customers are small, we expect their purchases to grow in future periods. We have continued to win new genomic customers despite the highly competitive nature of this market. An example of this occurred in Canada, where DNA Genotek is located. We signed a new customer who is building a biobank with over 16 sites planned over the next two years. We were able to beat the competition for this account with a combination of superior product technology and services. On the international front, our efforts to expand in the genomics space in China is also starting to pay dividends. We have continued to win new customers in this country and are now seeing repeat orders from two fairly recent new customers.

Microbiome

Our microbiome business also continues to gain traction. Microbiome-related revenues are up approximately 164% and 188% for the three and nine month periods ended September 30, 2016, respectively, compared to the same periods in 2015. We have added a number of new customers, particularly in the pharma microbiome space. We believe this is a good sign for future growth in this part of our business. We are also intensifying

our sales activities in emerging markets, such as Russia and China. We believe our microbiome offerings are potentially attractive to this part of the world in addition to the U.S. and European markets.

Tuberculosis

In the area of tuberculosis, we are continuing with our studies to support future endorsement of our TB products by the WHO. We have now completed more than 50% of our field studies. Our expectation is that these studies should be finished by year end or early next year. We are targeting receipt of WHO endorsement sometime in 2017.

Operations Update – Doug Michels

Another area I would like to address is the significant work under way in our operations area, in order to meet increasing demand for our diagnostic products.

We recently received delivery of our second automated production line for the assembly of OraQuick® platform products. This equipment will supplement our current automated and manual production lines in Bethlehem and a manual line at our Thailand contract manufacturer to support future business growth. The new equipment will be operational in the second quarter of 2017 after installation and validation are completed and related regulatory approvals are received.

The second automated line's capacity, when fully operational in 2017, will be approximately 8.0 million devices per year. This is approximately 85% higher output than the current automated production line. Additionally, the new automated production line requires 1/3 less operator support than the original line which will result in more efficient, lower cost device assembly.

The second automated line will be capable of producing all OraQuick® platform products and will be approved initially for our HIV and HCV products. OraQuick® Ebola and OraQuick® Zika devices can be produced on the automated lines in the future with

additional validation and regulatory approval. The additional production capacity for OraQuick® platform products will support our growth initiatives in the infectious disease markets.

Analyst Day – Doug Michels

A final point I want to mention is the analyst day we have planned at the NASDAQ Marketsite, located in New York City on November 29, 2016. This will be similar to the analyst days we have held in the past. At this event, you will get to hear from several members of our management team who will address areas of our business of interest to the investment community. These presentations will be webcast and the written materials used in the presentations will be broadly disseminated to the public prior to the event. Additional details on the day will be published in the next few weeks.

Conclusion

So, in summary, we delivered solid financial performance in the third quarter. We are executing against our key strategic priorities and we anticipate continued growth primarily from our international HIV, worldwide HCV and molecular collection systems businesses. On the expense side, we remain vigilant in driving increased efficiencies across our global organization. As a result, we believe OraSure is well positioned for future success.

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 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 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”) or 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 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 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.