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): August 3, 2016

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

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

220 East First Street **Bethlehem, Pennsylvania**	**18015-1360**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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

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

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

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

Item 2.02 – Results of Operations and Financial Condition.

On August 3, 2016, OraSure Technologies, Inc. (the "Company") issued a press release announcing its consolidated financial results for the quarter ended June 30, 2016, and providing financial guidance for the third 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 August 3, 2016, the Company held a webcast conference call with analysts and investors, during which Douglas A. Michels, the Company's President and Chief Executive Officer, and Ronald H. Spair, the Company's Chief Financial Officer and Chief Operating Officer, discussed the Company's consolidated financial results for the quarter ended June 30, 2016, provided financial guidance for the third 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 August 3, 2016, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2016, and providing financial guidance for the third quarter of 2016.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2016 Analyst/ Investor Conference Call Held August 3, 2016.

Signatures

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

Date: August 3, 2016

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

Index to Exhibits

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Exhibit 99.1

OraSure Technologies, Inc.

Company Contact:

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

OraSure Announces 2016 Second Quarter Financial Results

BETHLEHEM, PA – August 3, 2016 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a leader in point-of-care diagnostic tests and specimen collection devices, today announced its consolidated financial results for the three and six months ended June 30, 2016.

Financial Highlights

- Consolidated net revenues for the second quarter of 2016 were $31.4 million, a 3% increase from the second quarter of 2015. Consolidated net revenues for the six months ended June 30, 2016 were $60.4 million, a 5% increase from the comparable period of 2015.
- Net revenues from sales of the Company's OraQuick® rapid HCV test were $3.2 million for the second quarter of 2016, representing a 37% increase over the second quarter of 2015. Net revenues for the OraQuick® rapid HCV test were $6.1 million for the six months ended June 30, 2016, a 36% increase from the comparable period of 2015.
- Net revenues from international sales of the Company's OraQuick® HIV test were $2.0 million for the second quarter of 2016, representing a 230% increase over the second quarter of 2015. Net international revenues for the OraQuick® HIV test were $2.8 million for the six months ended June 30, 2016, an 83% increase from the comparable period of 2015.
- The Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), contributed $8.4 million in net revenues during the second quarter of 2016, which represents a 4% increase over the second quarter of 2015. DNAG net revenues during the six months ended June 30, 2016 were $15.3 million, a 3% increase from the comparable period in 2015.

- Consolidated net income for the second quarter of 2016 was $3.8 million, or $0.07 per share on a fully-diluted basis, which compares to consolidated net income of $2.0 million, or $0.03 per share on a fully-diluted basis, for the second quarter of 2015. Consolidated net income for the six months ended June 30, 2016 was $6.3 million, or $0.11 per share on a fully-diluted basis, which compares to consolidated net income of $2.1 million, or $0.04 per share, for the comparable period of 2015.
- Cash and short-term investments totaled $113.4 million and working capital amounted to $120.3 million at June 30, 2016.

“We are pleased with the Company’s financial performance for the second quarter of 2016, which exceeded expectations on both the top and bottom lines,” said Douglas A. Michels, President and CEO of OraSure Technologies. “Continued growth in sales of our infectious disease and molecular collection systems products were the main drivers behind this performance. We expect long-term growth from both of these businesses and see the international marketplace as an emerging and increasingly important strategic priority for our Company.”

Financial Results

Consolidated net product revenues for both the second quarter and first six months of 2016 increased 5% over the comparable periods of 2015, primarily as a result of higher sales of the Company’s OraQuick® HCV, OraQuick® HIV, and molecular collection systems products. These increases were partially offset by lower sales of the Company’s risk assessment products and the absence of sales of the Company’s OraQuick® Ebola Rapid Antigen test. The increase for the six month period also included higher sales of the Company’s cryosurgical systems products.

Consolidated other revenues for the second quarter and first six months of 2016 were $3.8 million and $7.6 million, respectively. This compares to consolidated other revenues for the second quarter and first six months of 2015 of $4.1 million and $7.4 million, respectively. Exclusivity revenue recognized under the Company’s HCV co-promotion agreement with AbbVie for the second quarter and first six months of 2016 and 2015 was $3.4 million and $6.7 million, respectively. Other revenue in the second quarter of 2016 and 2015 included $417,000 and $714,000, respectively, of Ebola-related funding received from the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response’s Biomedical Advanced Research and Development Authority (“BARDA”). Other revenue for the first six months of 2016 and 2015 included $899,000 and $714,000, respectively, in BARDA funding.

Consolidated gross margin for the three and six months ended June 30, 2016 was 67% and 68%, respectively. Consolidated gross margin for the three and six months ended June 30, 2015 was 68% and 66%, respectively. Gross margin for

the current quarter decreased primarily due to an unfavorable product mix partially offset by lower scrap and spoilage costs. Gross margin for the six-month period increased largely due to lower scrap and spoilage costs, a more favorable product mix, decreased royalty expense, and an increase in Ebola-related funding from BARDA.

Consolidated operating expenses decreased to $16.7 million during the second quarter of 2016 compared to $17.9 million in the second quarter of 2015. For the six months ended June 30, 2016, consolidated operating expenses were $34.4 million, a decrease from the $35.3 million reported for the six months ended June 30, 2015. The quarterly decrease was largely due to lower costs associated with the AbbVie HCV co-promotion agreement partially offset by higher legal costs. The decrease in the six-month period was largely due to lower research and development expenses and lower costs associated with the AbbVie co-promotion agreement, partially offset by increased legal and consulting costs.

The Company’s cash and short-term investment balance totaled $113.4 million at June 30, 2016 compared to $101.3 million at December 31, 2015. Working capital was $120.3 million at June 30, 2016 compared to $111.5 million at December 31, 2015. For the six months ended June 31, 2016, the Company generated $16.7 million in cash from operations.

Third Quarter 2016 Outlook

The Company expects consolidated net revenues to range from $31.25 to $31.75 million and is projecting consolidated net income of between $0.07 and $0.08 per share for the third quarter of 2016.

Financial Data

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

Unaudited

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Results of Operations				
Net revenues	$31,359	$30,388	$60,448	$57,476
Cost of products sold	10,274	9,692	19,050	19,782
Gross profit	21,085	20,696	41,398	37,694
Operating expenses:				
Research and development	2,985	2,996	5,351	6,436
Sales and marketing	7,397	8,904	16,103	16,788
General and administrative	6,354	6,075	12,896	12,040
Total operating expenses	16,736	17,975	34,350	35,264
Operating income	4,349	2,721	7,048	2,430
Other income (expense)	(340)	(95)	(532)	314
Income before income taxes	4,009	2,626	6,516	2,744
Income tax expense	173	658	234	663
Net income	$ 3,836	$ 1,968	$ 6,282	$ 2,081
Earnings per share:				
Basic	$ 0.07	$ 0.03	$ 0.11	$ 0.04
Diluted	$ 0.07	$ 0.03	$ 0.11	$ 0.04
Weighted average shares:				
Basic	55,543	56,453	55,497	56,398
Diluted	56,208	56,687	56,144	56,678

Summary of Net Revenues by Market and Product (Unaudited)

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$12,949	$11,792	10%	41%	39%
Risk assessment testing	3,159	3,466	(9)	10	11
Cryosurgical systems	3,041	2,953	3	10	10
Molecular collection systems	8,433	8,102	4	27	27
Net product revenues	27,582	26,313	5	88	87
Other	3,777	4,075	(7)	12	13
Net revenues	$31,359	$30,388	3%	100%	100%

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
Market	2016	2015	% Change	2016	2015
Infectious disease testing	$24,317	$23,288	4%	40%	40%
Risk assessment testing	6,265	6,473	(3)	10	11
Cryosurgical systems	6,922	5,498	26	12	10
Molecular collection systems	15,323	14,819	3	25	26
Net product revenues	52,827	50,078	5	87	87
Other	7,621	7,398	3	13	13
Net revenues	$60,448	$57,476	5%	100%	100%

HIV Revenues	Three Months Ended June 30, 2016	2015	% Change	Six Months Ended June 30, 2016	2015	% Change
Domestic	$5,886	$6,593	(11)%	$11,588	$12,601	(8)%
International	1,969	596	230	2,824	1,544	83
Domestic OTC	1,739	1,719	1	3,262	3,280	(1)
Net product revenues	$9,594	$8,908	8%	$17,674	$17,425	1%

HCV Revenues	Three Months Ended June 30, 2016	2015	% Change	Six Months Ended June 30, 2016	2015	% Change
Domestic	$1,788	$1,693	6%	$ 3,689	$ 2,889	28%
International	1,428	646	121	2,430	1,619	50
Net product revenues	3,216	2,339	37	6,119	4,508	36
Amortization of exclusivity payments	3,360	3,361	0	6,722	6,684	1
Net HCV-related revenues	$6,576	$5,700	15%	$12,841	$11,192	15%

Cryosurgical Systems Revenues	Three Months Ended June 30, 2016	2015	% Change	Six Months Ended June 30, 2016	2015	% Change
Domestic professional	$1,145	$1,008	14%	$ 2,699	$ 1,668	62%
International professional	211	142	49	446	498	(10)
Domestic OTC	345	108	219	723	163	344
International OTC	1,340	1,695	(21)	3,054	3,169	(4)
Net cryosurgical systems revenues	$3,041	$2,953	3%	$ 6,922	$ 5,498	26%

Condensed Consolidated Balance Sheets (Unaudited)

	June 30, 2016	December 31, 2015
Assets		
Cash	$ 105,701	$ 94,094
Short-term investments	7,736	7,225
Accounts receivable, net	18,436	19,265
Inventories	11,366	13,242
Other current assets	3,136	2,888
Property and equipment, net	20,200	20,083
Intangible assets, net	12,020	12,591
Goodwill	19,541	18,250
Other non-current assets	1,784	1,683
Total assets	$ 199,920	$ 189,321
Liabilities and Stockholders' Equity		
Accounts payable	$ 3,956	$ 5,087
Deferred revenue	13,822	9,735
Other current liabilities	8,293	10,412
Other non-current liabilities	2,018	1,768
Deferred income taxes	3,043	2,883
Stockholders' equity	168,788	159,436
Total liabilities and stockholders' equity	$ 199,920	$ 189,321

Additional Financial Data (Unaudited)	Six months ended June 30, 2016	2015
Capital expenditures	$ 2,729	$ 1,145
Depreciation and amortization	$ 2,778	$ 2,849
Stock-based compensation	$ 2,942	$ 3,008
Cash provided by (used in) operating activities	$ 16,741	$ (3,421)

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2016 second quarter financial results, certain business developments and financial guidance for the third 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 #46406766 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 August 10, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #46406766.

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 to identify, complete, integrate and realize the full benefits of future acquisitions; impact of

competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 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 Second Quarter

Analyst/Investor Conference Call

August 3, 2016

Prepared Remarks of Douglas A. Michels and Ronald H. Spair

Please see "Important Information" at the conclusion of the following prepared remarks.

Introduction – Doug Michels

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

We are pleased to report that our 2016 second quarter results have exceeded expectations on both the top and bottom lines.

- Consolidated net revenues for Q2 were $31.4 million, a 3% increase over the same period of 2015. Consolidated net product revenue increased 5% in the period. These increases resulted primarily from higher infectious disease and molecular collection systems sales.
- International HIV sales, driven primarily by additional orders for our new OraQuick® HIV self-test in Africa, increased 230% from Q2 of 2015.
- Sales of our OraQuick® HCV test increased 37% over Q2 of 2015. This increase reflects both higher domestic and international sales.
- Molecular collection systems revenues rose 4% from the prior year quarter, largely due to higher sales to customers in the commercial genomics market as well as revenue growth from our portfolio of microbiome products.
- We exceeded our bottom line guidance with $3.8 million in consolidated net income for the second quarter. This represents a $1.9 million improvement from the year-ago quarter.

Ron will provide further detail on our Q2 financial performance along with our guidance for the third quarter. I will then discuss some additional business developments.

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

Second Quarter 2016 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our second quarter 2016 consolidated net revenues increased 3% to $31.4 million, compared to $30.4 million reported in 2015. Our consolidated net product revenues of $27.6 million increased 5%, largely as a result of higher sales of our OraQuick® HCV, OraQuick® HIV and molecular collection systems products, partially offset by lower sales of our risk assessment products and the absence of sales of our OraQuick® Ebola product during the current quarter.

Other revenues were $3.8 million in the current quarter, of which $3.4 million represents the recognition of exclusivity revenue under the AbbVie HCV co-promotion agreement and $417,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the second quarter of 2015 also included $3.4 million of exclusivity revenue from the AbbVie agreement and $714,000 of BARDA funding.

HCV product revenues increased 37% to $3.2 million in Q2 from $2.3 million in the prior year. International sales of our HCV test in the second quarter of 2016 rose 121% to $1.4 million from $646,000 in the same period last year primarily due to the expansion of our business in Asia and higher sales to a multi-national humanitarian organization. Domestic OraQuick® HCV product sales increased 6% in the second quarter of 2016 to $1.8 million from $1.7 million in the prior year period. This continued expansion of our core domestic HCV business resulted from higher sales to current customers who have expanded their HCV testing programs and the addition of new programs primarily in the public health market.

In 2015, we began selling our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. Sales of this product contributed $396,000 in product revenues during the second quarter of 2015. We did not have similar sales in the second quarter of 2016. We do believe Ebola sales in future periods are likely, given international surveillance efforts, but the timing and magnitude is uncertain.

International sales of our professional HIV product increased 230% to $2.0 million in the second quarter of 2016, compared to $596,000 in the second quarter of 2015. This increase is largely due to the continued shipment of product in support of an HIV self-testing program launched in Africa during Q1 and higher sales in Europe. Domestic sales of our professional HIV product decreased 11% to $5.9 million in the second quarter of 2016, compared to $6.6 million in the second quarter of 2015.

Sales of our OraQuick® In-Home test remained flat at $1.7 million in the second quarter of 2016 and 2015.

Our molecular collection systems revenues rose 4% to a record $8.4 million in the second quarter of 2016 compared to $8.1 million in the second quarter of 2015. Sales of our Oragene® product to commercial customers increased 7%, largely due to ordering patterns of existing customers partially offset by the absence of sales from two large U.S. customers experiencing financial difficulties. The Company has no unreserved collections exposure related to these two customers. Academic sales decreased 7% primarily as a result of the timing of orders placed by existing customers.

Second quarter 2016 cryosurgical revenues remained flat at $3.0 million in the second quarter of 2016 and 2015.

Gross Margin – Ron Spair

Gross margin for the second quarter of 2016 was 67% compared to 68% reported for the second quarter of 2015. Margin for the current quarter decreased primarily due to an unfavorable product mix, partially offset by lower scrap and spoilage costs.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the second quarter of 2016 were $16.7 million compared to $17.9 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 higher legal costs.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of $3.8 million, or $0.07 per share on a fully diluted basis, for the second quarter of 2016, compared to net income of $2.0 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 June 30, 2016 was $113.4 million compared to $101.3 million at December 31, 2015. Cash generated by operating activities in the second quarter of 2016 was $11.9 million compared to $3.2 million in the second quarter of 2015.

Third Quarter 2016 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the third quarter of 2016, we are projecting consolidated net revenues of approximately $31.25 million to $31.75 million. We are also projecting consolidated net income of approximately $0.07 to $0.08 per share. Our results for Q3 are projected to be lower than previously estimated for a number of reasons. We are projecting lower international cryosurgical OTC sales resulting from a demand reduction, lower Ebola funding from BARDA due to a shift in our development timeline and lower Ebola product sales.

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

Business Update – Doug Michels

Thanks, Ron.

Infectious Disease Testing – Doug Michels

The highlight for the quarter was our infectious disease testing business. As you can see from Ron's overview, revenue growth for the second quarter was largely the result of continued progress in international markets.

HIV Self-Test

A primary example of this was the $1.2 million in sales of our new OraQuick® HIV self-test into Africa. These tests were purchased by Population Services International ("PSI"), a leading global health organization. PSI has launched the Self-Testing in Africa or "STAR" project with support from UNITAID, the World Health Organization ("WHO") and health officials from Malawi, Zambia and Zimbabwe. As noted on prior calls, this is a pilot program being funded by UNITAID designed to deploy approximately 750,000 OraQuick® HIV self-tests we developed specifically for developing markets.

PSI has advised us that our test has been well received in the field. Our expectation is that the initial orders from PSI will lead to a much larger, long-term opportunity that is expected to expand into other countries in Africa, Latin America and Asia. To help ensure the long-term success of this effort, we are pursuing pre-qualification of our HIV self-test by the WHO and are targeting September for our submission. WHO pre-qualification is important to be eligible for sustainable funding from sources such as the Global Fund, UNITAID and PEPFAR. Sales of our self-test to PSI more than offset the decline in our domestic HIV business during the second quarter.

OraQuick® HCV

Turning to HCV, the 37% overall increase in product revenues for the second quarter was largely driven by a 121% increase in international sales, compared to the second quarter of 2015.

As with our HIV business, we believe the international marketplace is becoming an increasingly important opportunity for our OraQuick® HCV test. As recently disclosed, we are in the late stages of fulfilling the requirements to secure the largest new supply contract for rapid tests in our company's history. Since our last update, the contract has been signed by both parties and we are completing some additional ancillary documents required for this contract to become fully effective. The contract calls for us to supply a foreign government with $18 million of product, the vast majority of which is our HCV rapid test. The delivery period ramps over a 12-month contract period and supports a nationwide testing and treatment program with the goal of eliminating HCV infection across the country. There are a growing number of countries evaluating similar country-wide HCV elimination programs.

We are moving forward with the production and logistics planning required to fulfill this agreement. We expect to release additional details and timing specific to this new contract in the next 30 to 45 days, at which time we anticipate providing an update on guidance.

On the domestic front, our HCV product sales grew primarily as a result of continued growth in the U.S. public health market. Part of this growth was in support of the Southern City Rapid Hepatitis C Test and Link to Care Initiative, which was formally announced on July 25th in Philadelphia in support of National African American Hepatitis C Action Day. This initiative was announced by the National Black Leadership Commission on AIDS with the support of several industry partners, including OraSure and Gilead Sciences.

This initiative is focused on several southern cities, including, New Orleans and Baton Rouge, Louisiana, Columbia, South Carolina, and Birmingham and Tuskegee, Alabama, and specifically seeks to:

- Expand rapid HCV testing in public and community settings;
- Educate and mobilize community leadership to respond to various barriers that limit access to HCV testing; and

- Collect data from this testing in order to demonstrate program effectiveness.

Testing under this initiative is already underway and we expect additional product orders to be filled this year under this initiative.

Rapid Zika Test

Turning to one of our newer infectious disease products, we continue to pursue development of a rapid Zika antibody test. Although there are currently molecular tests available for Zika, these tests have limited utility because of the short window of time when viral antigen can be detected in infected patients. Because IgM and IgG antibodies are present in the body for longer periods, we believe there is a significant need and utility for a rapid antibody test.

We have made good progress optimizing our OraQuick® platform to meet the performance characteristics for Zika and are optimistic that we will be successful in our development efforts.

Additionally, we have made significant progress in securing funding for the development, regulatory approval and commercial scale up of our OraQuick® Zika Rapid Test. We expect to share specifics on funding in the very near term.

New Ebola Sales

As previously discussed, our OraQuick® Ebola antigen test is the only rapid point-of-care test with FDA Emergency Use Authorization and WHO Emergency Use approval for testing both live patients and cadavers. Our product continues to be used for surveillance in West Africa. We are also making good progress towards obtaining 510(k) clearance for our Ebola test, with funding under our previously announced contract with BARDA.

So in summary, there were a number of positive developments in our infectious disease business and from these developments, we see several noteworthy trends.

- There are significant emerging opportunities for both our OraQuick® HIV and OraQuick® HCV products outside the United States. We intend to pursue these markets aggressively and expect that international markets will become increasingly important for our Company.
- Second, we continue to strengthen our position as the world-wide leader in HIV self-testing. As you know, our OraQuick® In-Home HIV test is the first and only rapid HIV self-test approved by the FDA for use by consumers. Since its approval, we have sold over 1.0 million In-Home HIV tests in the U.S. alone. With the launch of the STAR self-test initiative in Africa and the expected expansion of self-testing to other countries and geographies, we believe our line of HIV self-tests could become a much more significant contributor to our infectious disease business.
- Lastly, the successful development of our Ebola test and our continued progress on Zika has reaffirmed the strength and versatility of our OraQuick® diagnostic platform. As the work on these important new products has progressed, we have expanded and strengthened our relationships with global health organizations and governments. We continue to build on our reputation as a reliable, preferred source of diagnostic solutions for emerging diseases around the world.

Molecular Collections Systems – Doug Michels

Turning to our molecular collections business –

Revenues for this segment for both the quarter and six months ended June 30, 2016 were record highs. It is important to note that the somewhat modest quarterly growth compared to 2015 was primarily related to the financial misfortune of two large commercial accounts, which filed for bankruptcy protection. Excluding these customers, our molecular collection revenues for the second quarter and first six months of 2016 would have grown 21% and 19%, respectively.

Genomics

We continue to generate the vast majority of our molecular collections system revenues in the genomics market, split between academic and commercial customers. During the second quarter, the revenue mix returned to more normal levels of approximately two-thirds commercial and one-third academic research. Overall, year to date, the split is sitting at 60%/40% commercial to academic.

We continue to bring on a steady stream of new customers. As indicated recently, we entered into a supply agreement for our DNA specimen collection kit with a genomics company that will be launching a wide array of services. This is an exciting and significant opportunity that we expect would have a very positive impact beginning in 2017. We expect to name this new customer and share details about our plans to work together in the next several months.

As discussed on prior calls, we are also supplying product for both a study on the epidemiology of aging and a study on autism conducted by the Simons Foundation Autism Research Institute. We are now seeing the revenues generated by these contracts materialize in our financial results.

Microbiome

Microbiome revenues are gaining traction with over 200% growth for the first six months of 2016 compared to the year ago period. Our customer mix is more heavily weighted on the research side, with approximately a 75%/25% split between academic and commercial. The fact that we have commercial sales is evidence of the utility of metagenomics in both biotech and pharma sponsored R & D activities and in a growing number of clinical trials collecting microbiome information for purposes of patient stratification. One new opportunity of note is a multi-year supply agreement we signed for our OMNIgene®●Gut collection kits with a direct-to-consumer microbiome company in Eastern Europe. This customer intends to use gut microbiome data for nutritional purposes.

Last quarter, we also discussed a multi-year supply agreement for microbiome-wide association studies. One study out of the University of Michigan is using a novel protocol to isolate and analyze short chain fatty acids from stool collected with our device as an indication of inflammation in the gut. This protocol has been published in peer reviewed literature and is now available for our customers to use. We anticipate that studies such as this will help drive further utility and growth for our microbiome collection device.

Tuberculosis

We are also continuing to broaden awareness and acceptance of OMNIgene® ● Sputum for the stabilization of tuberculosis specimens. WHO endorsement studies are set to start in both Peru and Ethiopia this quarter and are expected to be completed by the first quarter of 2017. After completion, we will submit this data to the WHO for endorsement which we would expect to receive in 2017. In the meantime, we see increasing interest as multiple countries and laboratories continue to evaluate our product.

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Business Development

A final point I want to address is business development. We are often asked questions regarding our plans for M & A activity. While I cannot comment on specifics, I would emphasize that acquiring new products, technologies or companies is an important strategic priority for our Company. Our primary focus for this activity is in the molecular and infectious disease areas. There are a number of opportunities under active review and we will apply the same general criteria that brought us DNA Genotek and caused us to pass on other transactions.

Conclusion

So, in closing, we delivered solid financial performance during the second quarter and made very good progress on all of our key strategic objectives. We expect ongoing growth from our HCV and molecular collection systems businesses and see the international marketplace as an emerging and increasingly important strategic priority for our overall business. With a strong balance sheet, we are in a great position to acquire products or companies to enhance our growth. Over the back half of the year, we will be looking to wind down our expenditures in support of the AbbVie relationship. Our activities and expenditures in support of the patient care database, physician training, consultative services related to reimbursement, and our sampling program, should conclude by year-end. Additionally, we will have no further obligations related to their promotion of the AbbVie patient care model. Beyond these activities, we will continue our efforts to drive efficiencies across our global organization. We will share updates on all of these fronts as the year progresses.

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 to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or

impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 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.