
**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): May 4, 2016

OraSure Technologies, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-16537
(Commission
File Number)

36-4370966
(I.R.S. Employer
Identification No.)

220 East First Street
Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

18015-1360
(Zip Code)

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 – Results of Operations and Financial Condition.

On May 4, 2016, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended March 31, 2016, and providing financial guidance for the second 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 May 4, 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 March 31, 2016, provided financial guidance for the second 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 4, 2016, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2016, and providing financial guidance for the second quarter of 2016.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2016 Analyst/Investor Conference Call Held May 4, 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: May 4, 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
610-882-1820
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OraSure Announces 2016 First Quarter Financial Results

BETHLEHEM, PA – May 4, 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 first quarter ended March 31, 2016.

Financial Highlights

- Consolidated net revenues for the first quarter of 2016 were \$29.1 million, a 7% increase from the first quarter of 2015.
- Net domestic revenues from sales of the Company's OraQuick® rapid HCV test were \$1.9 million for the first quarter of 2016, representing a 59% increase over the first quarter of 2015. Total HCV-related revenues, including exclusivity payments recognized under the HCV co-promotion agreement with AbbVie, were \$6.3 million, as compared to \$5.5 million for the first quarter of 2015.
- The Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), contributed \$6.9 million in net revenues during the first quarter of 2016, which represents a 3% increase over the first quarter of 2015.
- Sales of the Company's cryosurgical systems products were \$3.9 million, representing a 53% increase over the comparable quarter of 2015.
- Consolidated net income for the first quarter of 2016 was \$2.4 million, or \$0.04 per share on a fully-diluted basis, which compares to a consolidated net income of \$113,000, or \$0.00 per share, for the first quarter of 2015.

- Cash and short-term investments totaled \$102.2 million and working capital amounted to \$114.0 million at March 31, 2016.

“We are pleased with the Company’s financial performance for the first quarter of 2016,” said Douglas A. Michels, President and CEO of OraSure Technologies. “Continued growth in sales of our OraQuick® HCV and molecular collection systems products and improved performance by our cryosurgical systems business were the main drivers behind this performance. We expect to deliver continued profitable results during the remaining quarters of the year.”

Financial Results

Consolidated net product revenues for the first quarter of 2016 increased 6% over the comparable period of 2015, primarily as a result of higher sales of the Company’s cryosurgical systems, OraQuick® HCV and molecular collection systems products. These increases were partially offset by lower sales of the Company’s OraQuick® professional HIV product.

Consolidated other revenues were \$3.8 million and \$3.3 million for the first quarter of 2016 and 2015, respectively. Amounts for both quarters included exclusivity payments recognized under the Company’s HCV co-promotion agreement with AbbVie. Other revenue for the current quarter also included 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”).

Consolidated gross margin for the three months ended March 31, 2016 was 70% compared to 63% for the three months ended March 31, 2015. Gross margin for the current quarter improved largely due to a more favorable product mix, a reduction in royalty expense and scrap and spoilage costs, and the Ebola-related funding from BARDA.

Consolidated operating expenses increased to \$17.6 million during the first quarter of 2016 compared to \$17.3 million in the comparable period of 2015. This increase was largely due to higher costs associated with the AbbVie co-promotion agreement and increased general and administrative expenses due to higher consulting, staffing, and legal costs. These increases were partially offset by lower research and development expenses.

The Company’s cash and short-term investment balance totaled \$102.2 million at March 31, 2016 compared to \$101.3 million at December 31, 2015. Working capital was \$114.0 million at March 31, 2016 compared to \$111.5 million at December 31, 2015. For the three months ended March 31, 2016, the Company generated \$4.7 million in cash from operations.

Second Quarter 2016 Outlook

The Company expects consolidated net revenues to range from \$30.5 to \$31.5 million and is projecting consolidated net income of between \$0.04 and \$0.05 per share for the second quarter of 2016.

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

Unaudited

	Three months ended March 31,	
	2016	2015
Results of Operations		
Net revenues	\$29,089	\$27,088
Cost of products sold	8,776	10,090
Gross profit	<u>20,313</u>	<u>16,998</u>
Operating expenses:		
Research and development	2,366	3,440
Sales and marketing	8,706	7,884
General and administrative	<u>6,542</u>	<u>5,965</u>
Total operating expenses	<u>17,614</u>	<u>17,289</u>
Operating income (loss)	2,699	(291)
Other income (expense)	<u>(192)</u>	<u>409</u>
Income before income taxes	2,507	118
Income tax expense	<u>61</u>	<u>5</u>
Net income	<u>\$ 2,446</u>	<u>\$ 113</u>
Earnings per share:		
Basic	<u>\$ 0.04</u>	<u>\$ 0.00</u>
Diluted	<u>\$ 0.04</u>	<u>\$ 0.00</u>
Weighted average shares:		
Basic	<u>55,451</u>	<u>56,343</u>
Diluted	<u>56,079</u>	<u>57,173</u>

Summary of Net Revenues by Market and Product (Unaudited)

<u>Market</u>	<u>Three Months Ended March 31,</u>				
	<u>Dollars</u>		<u>% Change</u>	<u>Percentage of Total Net Revenues</u>	
	<u>2016</u>	<u>2015</u>		<u>2016</u>	<u>2015</u>
Infectious disease testing	\$11,368	\$11,495	(1)%	39%	43%
Risk assessment testing	3,105	3,008	3	11	11
Cryosurgical systems	3,882	2,545	53	13	9
Molecular collection systems	6,890	6,717	3	24	25
Net product revenues	25,245	23,765	6	87	88
Other	3,844	3,323	16	13	12
Net revenues	<u>\$29,089</u>	<u>\$27,088</u>	7%	<u>100%</u>	<u>100%</u>

<u>HIV Revenues</u>	<u>Three Months Ended March 31,</u>		
	<u>2016</u>	<u>2015</u>	<u>% Change</u>
Domestic	\$5,703	\$6,007	(5)%
International	854	948	(10)
Domestic OTC	1,523	1,561	(2)
Net product revenues	<u>\$8,080</u>	<u>\$8,516</u>	(5)%

<u>HCV Revenues</u>	<u>Three Months Ended March 31,</u>		
	<u>2016</u>	<u>2015</u>	<u>% Change</u>
Domestic	\$1,900	\$1,197	59%
International	1,001	972	3
Net product revenues	2,901	2,169	34
Amortization of exclusivity payments	3,362	3,323	1
Net HCV-related revenues	<u>\$6,263</u>	<u>\$5,492</u>	14%

<u>Intercept® Revenues</u>	<u>Three Months Ended</u> <u>March 31,</u>		
	<u>2016</u>	<u>2015</u>	<u>%</u> <u>Change</u>
Net Intercept® revenues	\$1,891	\$1,575	20%

<u>Cryosurgical Systems Revenues</u>	<u>Three Months Ended</u> <u>March 31,</u>		
	<u>2016</u>	<u>2015</u>	<u>%</u> <u>Change</u>
Domestic professional	\$1,554	\$ 661	135%
International professional	235	357	(34)
Domestic OTC	378	55	587
International OTC	1,715	1,472	17
Net cryosurgical systems revenues	<u>\$3,882</u>	<u>\$2,545</u>	53%

Condensed Consolidated Balance Sheets (Unaudited)

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
<u>Assets</u>		
Cash	\$ 94,558	\$ 94,094
Short-term investments	7,689	7,225
Accounts receivable, net	16,734	19,265
Inventories	12,325	13,242
Other current assets	3,029	2,888
Property and equipment, net	20,204	20,083
Intangible assets, net	12,616	12,591
Goodwill	19,422	18,250
Other non-current assets	1,902	1,683
Total assets	<u>\$ 188,479</u>	<u>\$ 189,321</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 5,287	\$ 5,087
Deferred revenue	7,236	9,735
Other current liabilities	7,821	10,412
Other non-current liabilities	2,070	1,768
Deferred income taxes	3,050	2,883
Stockholders' equity	163,015	159,436
Total liabilities and stockholders' equity	<u>\$ 188,479</u>	<u>\$ 189,321</u>

Additional Financial Data (Unaudited)	Three months ended	
	March 31,	
	2016	2015
Capital expenditures	\$1,593	\$ 437
Depreciation and amortization	\$1,354	\$ 1,409
Stock-based compensation	\$1,452	\$ 1,475
Cash provided by (used in) operating activities	\$4,744	\$(6,591)

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2016 first quarter financial results, certain business developments and financial guidance for the second 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 #83627952 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 May 11, 2016, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #83627952.

About OraSure Technologies

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

Important Information

This press release contains certain forward-looking statements, including with respect to expected revenues and earnings/loss per share. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; our ability to achieve financial and performance objectives under the HCV co-promotion agreement with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNAG to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain

needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 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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OraSure Technologies, Inc.

2016 First Quarter

Analyst/Investor Conference Call

May 4, 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 we exceeded expectations on both the top and bottom lines for the first quarter of 2016.

- Consolidated net revenues for Q1 were \$29.1 million, a 7% increase over the same period of 2015. This growth was driven by higher sales of our OraQuick® HCV, molecular collection systems and cryosurgical systems products.
- Domestic HCV sales increased 59% over Q1 of 2015. Total HCV-related revenues, which include exclusivity payments under our HCV co-promotion agreement with AbbVie, were \$6.3 million for the quarter.
- Molecular collection systems revenues rose 3% from the prior year quarter, largely due to higher sales to customers in the academic research market.
- Cryosurgical systems revenues rose 53% to \$3.9 million for the quarter.
- The revenue growth, combined with higher margins and lower operating expenses, generated \$2.4 million in consolidated net income for the first quarter.

Ron will provide further detail on our Q1 financial performance along with our expectations for the second quarter of 2016. I will then discuss some additional developments in our business.

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

First Quarter 2016 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our first quarter 2016 consolidated net revenues increased 7% to \$29.1 million, compared to \$27.1 million reported in 2015. Our consolidated net product revenues of \$25.2 million increased 6%, largely as a result of higher sales of our cryosurgical systems, OraQuick® HCV and molecular collection systems products, partially offset by lower sales of our professional OraQuick® HIV product and the absence of sales of our OraQuick® Ebola product.

Other revenues were \$3.8 million in the current quarter, of which \$3.3 million represents the recognition of exclusivity payments under the AbbVie HCV co-promotion agreement and \$482,000 represents revenue associated with Ebola-related funding we received from the Biomedical Advanced Research and Development Authority, or BARDA. Other revenues in the first quarter of 2015 also included \$3.3 million of AbbVie exclusivity payments.

HCV product revenues increased 34% to \$2.9 million in Q1 from \$2.2 million in the prior year. Domestic OraQuick® HCV product sales increased 59% in the first quarter of 2016 to \$1.9 million from \$1.2 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. International sales of our HCV test in the first quarter of 2016 increased 3% to \$1.0 million from \$972,000 in the same period last year primarily due to the expansion of our business in Asia. Total HCV-related revenues, including the AbbVie exclusivity payments, increased 14% to \$6.3 million in the first quarter of 2016 compared to \$5.5 million in the first quarter of 2015.

In 2015, we began selling our OraQuick® Ebola Rapid Antigen test to the CDC for field testing in Africa. Sales of this product contributed \$364,000 in product revenues during the first quarter of 2015. We did not have similar sales in the first quarter of 2016. We do believe Ebola sales in future periods are likely, given the current status of the disease and international surveillance efforts.

Domestic sales of our professional HIV product decreased 5% to \$5.7 million in the first quarter of 2016, compared to \$6.0 million in the first quarter of 2015. As previously communicated, we expect continued pressure on our professional HIV business in 2016.

International sales of our professional HIV product decreased 10% to \$854,000 in the first quarter of 2016, compared to \$948,000 in the first quarter of 2015. This decrease reflects lower sales into Africa as a result of customer ordering patterns and the variability of project-based business in that region, partially offset by an initial shipment in support of an HIV self-testing program launched in Africa and higher sales in Europe.

Sales of our OraQuick® In-Home test remained relatively flat at \$1.5 million in the current period from \$1.6 million in the first quarter of 2015.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line in the genomics market, increased 3% to \$6.9 million in the first quarter of 2016 compared to \$6.7 million in the first quarter of 2015. Sales to academic customers increased 37%, largely due to customer ordering patterns of existing customers coupled with the first quarter shipment of product to support a study on the epidemiology of aging. Commercial sales decreased 20% primarily as a result of two large purchases in the same period last year that did not repeat in this quarter. New customer sales helped to offset the absence of those purchases. We remain very confident in our ability to capitalize on the sample collection market.

First quarter 2016 cryosurgical revenues increased 53% to \$3.9 million from \$2.5 million in the first quarter of 2015. Domestic sales of our professional product increased 135% to

\$1.6 million in the first quarter of 2016 compared to \$661,000 in the first quarter of 2015, largely due to distributor ordering patterns. International sales of our professional product decreased 34% to \$235,000 from \$357,000 in the comparable period of 2015 due to increased competition from private label product. Sales of our domestic OTC product increased to \$378,000 in the first quarter of 2016 from \$55,000 in the first quarter of 2015 due to the launch of private-label product for two additional large pharmacy chains. Sales of our OTC products in the international markets increased 17% to \$1.7 million in the first quarter of 2016 compared to \$1.5 million in the first quarter of 2015, primarily as a result of the ordering patterns of our Latin American distributor.

Gross Margin – Ron Spair

Gross margin for the first quarter of 2016 was 70% compared to 63% reported for the first quarter of 2015. Margin for the current quarter benefited from a more favorable product mix, reductions in both royalty expenses and scrap and spoilage costs, and the Ebola-related funding received from BARDA.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the first quarter of 2016 were \$17.6 million compared to \$17.3 million in the comparable period of 2015. This increase was the result of higher detailing costs associated with our HCV co-promotion agreement with AbbVie, and increased staffing, commission, and consulting costs, partially offset by lower research and development spending and a favorable change in the exchange rate between the Canadian and U.S. dollars.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of \$2.4 million, or \$0.04 per share on a fully diluted basis, for the first quarter of 2016, compared to net income of \$113,000, or \$0.00 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 March 31, 2016 was \$102.2 million compared to \$101.3 million at December 31, 2015. Cash generated by operating activities in the first quarter of 2016 was \$4.7 million compared to a use of \$6.6 million in the first quarter of 2015. During the first quarter of 2016, we used \$2.7 million in cash to buy back stock under our previously authorized stock repurchase program. No additional purchases are currently planned under this program.

Second Quarter 2016 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the second quarter of 2016, we are projecting consolidated net revenues of approximately \$30.5 to \$31.5 million. We are also projecting consolidated net income of approximately \$0.04 to \$0.05 per share.

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

Business Update – Doug Michels

Thanks, Ron.

Molecular Collection Systems – Doug Michels

As noted earlier, DNA Genotek's revenues increased in the first quarter of 2016. We remain enthusiastic about the future prospects for this business as we continue to bring on a steady stream of new customers.

We continue to generate the vast majority of our molecular collection systems revenues in the genomics market, split between academic and commercial customers. During the first quarter, these revenues were split in roughly equal parts, which is a departure from our recent trend of 65% commercial and 35% academic research. As this part of our business returns to higher growth rates in future quarters, we would expect the revenue split to move closer to the historic norms.

During the last earnings call, I mentioned several examples of where our genomics business is becoming more diversified.

- We had a customer acquire product to support the longitudinal study on the epidemiology of aging that we discussed during our last call.
- We also provided collection kits, custom packaging and fulfillment services for a large, long-term study on autism conducted by the Simons Foundation Autism Research Institute. This customer launched an online research initiative called “SPARK” to recruit 50,000 individuals with autism and their family members. This is a three-year project that aims to be the largest autism study ever undertaken in the U.S. to advance understanding of the causes of autism and develop new treatments and support protocols. DNAG Genotek is providing a customized solution designed to facilitate home collection of DNA samples by study participants. A large order was placed for this study in the first quarter, and will be fulfilled over the next several years.
- I also mentioned that we have begun selling product to a personal genomics company in China for use in providing genetic analysis of ancestral traits, health risks, disease screening, drug reactions, genetic characteristics and nutrition metabolism. We received our first order from this customer in Q4 of last year and began shipping kits to them in March.

Microbiome and TB Markets

We have also previously mentioned two new business opportunities – the microbiome market and the infectious disease market focused on tuberculosis testing.

With additional microbiome revenues in Q1, our outlook for this important market continues to be quite positive. Interest in our products is growing with both new and repeat customers, and we are seeing more investment directed towards therapeutics and diagnostics in the microbiome space. Sample quality for these customers is important as they embark on early stage research and clinical trials and we believe our product

offerings can address this need. In this regard, we are working to broaden our portfolio by offering microbiome collection solutions for the tongue, gums and plaque as well as vaginal microbiome collections. We are also engaging with dozens of researchers planning population-scale microbiome-wide association studies which could eventually resemble the array-based genomics research studies of the early 2000s. Initiatives such as these further support our optimism for the microbiome market.

In the area of tuberculosis, we continue to pursue studies in support of the future endorsement of our TB products by the World Health Organization (“WHO”). We are also supporting many laboratories and researchers around the world as they conduct evaluations of our products.

Overall, we are very pleased with our molecular collections systems business. We expect sales in the genomics market to continue to be a strong growth contributor for our Company and we are excited about the opportunity to expand our molecular business segment, especially in the microbiome marketplace.

Infected Disease Testing – Doug Michels

Turning to our core infectious disease testing business, revenues were essentially flat when compared to the same quarter last year. Declines in our HIV professional business were offset by the continued strong growth in sales of our OraQuick® HCV test.

As indicated during our last call, an exciting opportunity for growth in our HIV business is through the sale of our OraQuick® HIV self-test in the international marketplace. We continue to work with Population Services International (“PSI”), a leading global health organization, along with UNITAID, the WHO and health officials from Malawi, Zambia and Zimbabwe, to implement the Self-Testing in Africa or “STAR” project. The STAR project is a pilot program being funded by UNITAID that will use the OraQuick® HIV self-test we developed specifically for the African marketplace. Initial shipments of our product were made during the first quarter and we expect to make additional shipments in Q2.

As Ron noted, domestic HIV sales declined 5% compared to Q1 of 2015, reflecting the continued impact of competition from fourth generation automated lab tests and other lower-cost point of care HIV tests. Although we expect the rate of decline in our domestic business to ease somewhat in 2016, largely due to some new marketing initiatives and a continued recognition of the value of our rapid HIV test, we expect the overall negative trend in this part of our business to continue.

HCV revenues for the first quarter grew nicely, largely driven by a 59% increase in domestic product sales compared to the first quarter of 2015. Growth in our HCV business is being generated primarily through the addition of new customers and testing programs in the public health market and then having those programs expand over time. Within the public health market, we are currently seeing demand from large NGO's, community-based health centers and Indian Health.

Turning to our OraQuick® Ebola Rapid Antigen Test, we recently received FDA Emergency Use Authorization for the use of this test on oral fluid samples collected from cadavers. As you may know, the handling of cadavers has been identified as a significant source of Ebola transmission in Africa. We also received WHO approval to list our product for use with both blood samples from live patients and oral fluid samples from cadavers. Our OraQuick® Ebola rapid antigen test is now the only rapid point-of-care test approved for testing of both live patients and cadavers. The combination of these claims expands the utility of our test as new cases of Ebola continue to appear. We believe there will likely be ongoing need for our test in light of the continued occurrence of the disease and the WHO's recommendation for ongoing surveillance in certain African countries.

Our success with Ebola has positioned us well to assist with the most recent global health issue, Zika infection. As you may know, Zika is transmitted primarily through infected mosquitoes although there have been confirmed reports of sexually transmitted infections and infection through blood transfusion. While many infected individuals may experience mild symptoms or remain entirely asymptomatic, there is evidence that Zika infection in pregnant women is linked to microcephaly, a serious birth defect. Accordingly, health officials have communicated the urgent need for an

accurate point-of-care test for Zika. We are actively engaged in a development program for rapid Zika assays on the OraQuick® platform and are currently pursuing external funding for this program.

Organizational Change

On the organizational front, we recently announced that Dr. Michael Reed has been appointed Senior Vice President – Research and Development and Chief Science Officer for our Company.

Mike brings more than 20 years of global experience in life sciences and diagnostics research and development across an extensive array of disciplines, including globally regulated IVD development and commercialization of molecular and cellular applications and systems. He joins OraSure from Beckman Coulter, a global diagnostics and life sciences company within Danaher.

We are excited that Mike has joined OraSure and look forward to his contributions as a member of our senior management team.

Governance Recognition

As a final point, I would like to mention that OraSure was recently recognized by *Forbes Magazine* as one of the top 100 most trustworthy companies. The list was created from more than 2,500 publicly-traded non-financial companies with market caps of \$250 million or more. The analysis defined the 100 top companies as those that have most consistently demonstrated transparent accounting practices and solid corporate governance. OraSure ranked number 22 in the small cap category and number 36 overall in the top 100.

Conclusion

So, in closing, we are off to a solid start in 2016. We expect continued growth from our HCV and molecular collection systems businesses with additional opportunities likely to come from the microbiome market and our rapid Ebola test. With over \$100 million in cash and no debt, we are in a strong financial position. Furthermore, we continue to explore opportunities to acquire products or companies that could enhance our growth rate, as well as options to improve our profitability. We will share updates on 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; our ability to achieve financial and performance objectives under the HCV co-promotion agreement with AbbVie, failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations

and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 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.