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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 6, 2015**

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**OraSure Technologies, Inc.**

(Exact Name of Registrant as Specified in Charter)

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**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**

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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 6, 2015, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended March 31, 2015, and providing financial guidance for the second quarter of 2015. 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 6, 2015, 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, 2015, provided financial guidance for the second quarter of 2015 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 6, 2015, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended March 31, 2015, and providing financial guidance for the second quarter of 2015.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. First Quarter 2015 Analyst/ Investor Conference Call Held May 6, 2015.

## 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.

Date: May 6, 2015

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett

Jack E. Jerrett

Senior Vice President, General Counsel and Secretary

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**Index to Exhibits**

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OraSure Technologies, Inc.

Company Contact:

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### OraSure Announces 2015 First Quarter Financial Results

**BETHLEHEM, PA** – May 6, 2015 – (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, 2015.

#### Financial Highlights

- Consolidated net revenues for the first quarter of 2015 were \$27.1 million, a 15% increase from the comparable period of 2014.
- Net product revenues for the Company's OraQuick® rapid HCV test were \$2.2 million for the first quarter of 2015, representing a 39% increase over the first quarter of 2014. Total HCV-related revenues, including exclusivity payments recognized under the HCV co-promotion agreement with AbbVie, were \$5.5 million for the first quarter of 2015, \$3.9 million higher than the same period last year.
- Net revenues generated by the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), were \$6.7 million during the first quarter of 2015, representing a 17% increase over the first quarter of 2014.
- Consolidated net income for the first quarter of 2015 was \$113,000, or \$0.00 per share, which compares to a net loss of \$5.6 million, or \$0.10 per share, for the first quarter of 2014. This improvement was primarily the result of the AbbVie exclusivity revenues of \$3.3 million and lower sales and marketing expenses.
- Cash and short term investments totaled \$89.5 million and working capital amounted to \$105.6 million at March 31, 2015.

“We are pleased with our financial performance for the first quarter,” said Douglas A. Michels, President and CEO of OraSure Technologies, Inc. “Increased HCV-related revenues and higher sales from our molecular collections systems business were the primary reasons for this performance and will set the stage for a successful year.”

### **Financial Results**

Consolidated net product revenues for the first quarter of 2015 increased 1% from the comparable period of 2014, primarily as a result of higher sales of the Company’s molecular collection systems, OraQuick® HCV and Intercept® products. These increases were partially offset by lower sales of the Company’s cryosurgical systems, OraQuick® professional HIV and OraQuick® In-Home HIV products.

Consolidated net revenues for the first quarter of 2015 also included \$3.3 million of exclusivity payments recognized under the Company’s HCV co-promotion agreement with AbbVie.

Consolidated gross margin for the three months ended March 31, 2015 was 63% compared to 59% for the three months ended March 31, 2014. Gross margin for the current quarter improved largely as a result of the \$3.3 million in AbbVie revenues.

Consolidated operating expenses decreased to \$17.3 million during the first quarter of 2015 compared to \$19.5 million in the comparable period of 2014. This decrease was primarily due to lower promotional expenses associated with the Company’s OraQuick® In-Home HIV test, partially offset by higher research and development costs and legal fees. Promotional expenses for the OraQuick® In-Home HIV test were \$432,000 and \$4.6 million for the first quarters of 2015 and 2014, respectively.

The Company’s cash and short-term investment balance totaled \$89.5 million at March 31, 2015 compared to \$97.9 million at December 31, 2014. Working capital was \$105.6 million at March 31, 2015 compared to \$104.8 million at December 31, 2014. For the three months ended March 31, 2015, the Company used \$6.6 million to fund operations.

### **Second Quarter 2015 Outlook**

The Company expects consolidated net revenues to range from \$29.0 to \$29.5 million and is projecting consolidated net income of approximately \$0.00 to \$0.01 per share for the second quarter of 2015.

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

**Unaudited**

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Results of Operations</b>		
Net revenues	\$27,088	\$23,537
Cost of products sold	10,090	9,610
Gross profit	<u>16,998</u>	<u>13,927</u>
Operating expenses:		
Research and development	3,440	2,481
Sales and marketing	7,884	11,340
General and administrative	5,965	5,724
Total operating expenses	<u>17,289</u>	<u>19,545</u>
Operating loss	(291)	(5,618)
Other income	409	118
Income (loss) before income taxes	118	(5,500)
Income tax expense	5	131
Net income (loss)	<u>\$ 113</u>	<u>\$ (5,631)</u>
Earnings (loss) per share:		
Basic and Diluted	<u>\$ 0.00</u>	<u>\$ (0.10)</u>
Weighted average shares:		
Basic	<u>56,343</u>	<u>55,762</u>
Diluted	<u>57,173</u>	<u>55,762</u>

**Summary of Net Revenues by Market and Product (Unaudited)**

<b>Market</b>	<b>Three Months Ended March 31,</b>				
	<b>Dollars</b>			<b>Percentage of Total Net Revenues</b>	
	<b>2015</b>	<b>2014</b>	<b>% Change</b>	<b>2015</b>	<b>2014</b>
Infectious disease testing	\$ 11,495	\$ 11,064	4%	43%	47%
Substance abuse testing	2,102	1,830	15	8	8
Cryosurgical systems	2,545	3,967	(36)	9	17
Molecular collection systems	6,717	5,759	17	25	24
Insurance risk assessment	906	917	(1)	3	4
Net product revenues	23,765	23,537	1	88	100
Other	3,323	—	100	12	—
Net revenues	<u>\$27,088</u>	<u>\$23,537</u>	15%	<u>100%</u>	<u>100%</u>

<b>HIV Revenues</b>	<b>Three Months Ended March 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>
	Domestic	\$6,007	\$6,618
International	948	558	70
Domestic OTC	1,561	1,953	(20)
Net product revenues	<u>\$8,516</u>	<u>\$9,129</u>	(7)%

<b>HCV Revenues</b>	<b>Three Months Ended March 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>% Change</b>
	Domestic	\$1,197	\$ 663
International	972	896	8
Net product revenues	2,169	1,559	39
Amortization of exclusivity payments	3,323	—	100
Net HCV-related revenues	<u>\$5,492</u>	<u>\$1,559</u>	252%



<u>Intercept® Revenues</u>	<u>Three Months Ended</u> <u>March 31,</u>		
	<u>2015</u>	<u>2014</u>	<u>%</u> <u>Change</u>
Net Intercept® revenues	\$1,575	\$1,290	22%

  

<u>Cryosurgical Systems Revenues</u>	<u>Three Months Ended</u> <u>March 31,</u>		
	<u>2015</u>	<u>2014</u>	<u>%</u> <u>Change</u>
Domestic professional	\$ 661	\$1,542	(57)%
International professional	357	310	15
Domestic over-the-counter	55	—	100
International over-the-counter	1,472	2,115	(30)
Net cryosurgical systems revenues	<u>\$2,545</u>	<u>\$3,967</u>	(36)%

#### Condensed Consolidated Balance Sheets (Unaudited)

	<u>March 31, 2015</u>	<u>December 31, 2014</u>
<u>Assets</u>		
Cash	\$ 85,547	\$ 92,867
Short-term investments	3,942	5,000
Accounts receivable, net	16,367	16,138
Inventories	15,619	15,763
Other current assets	1,708	1,446
Property and equipment, net	17,645	17,934
Intangible assets, net	15,581	17,505
Goodwill	19,913	21,734
Other non-current assets	1,320	1,246
Total assets	<u>\$ 177,642</u>	<u>\$ 189,633</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 5,037	\$ 7,148
Deferred revenue	5,492	8,043
Accrued expenses	7,005	11,271
Other non-current liabilities	1,311	1,234
Deferred income taxes	2,970	3,236
Stockholders' equity	155,827	158,701
Total liabilities and stockholders' equity	<u>\$ 177,642</u>	<u>\$ 189,633</u>

Additional Financial Data (Unaudited)	Three months ended	
	March 31,	
	2015	2014
Capital expenditures	\$ 437	\$ 647
Depreciation and amortization	\$ 1,409	\$ 1,539
Stock based compensation	\$ 1,475	\$ 1,406
Cash used in operating activities	\$ 6,591	\$ 7,668

### Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2015 first quarter financial results, certain business developments and financial guidance for the second quarter of 2015, 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 #19423338 or go to OraSure Technologies' web site, [www.orasure.com](http://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 13, 2015, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #19423338.

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

for the year ended December 31, 2014, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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OraSure Technologies, Inc.

2015 First Quarter

Analyst/Investor Conference Call

May 6, 2015

**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**

Thanks Rena. Good afternoon everyone and welcome to our call.

As indicated in our press release, 2015 is off to a good start.

- Our first quarter financial results exceeded our guidance on both the top and bottom lines.
- Our molecular collections systems business delivered another strong quarter, with revenues up 17% over the prior year period.
- Sales of our OraQuick® rapid HCV test increased 39% over the first quarter of 2014. This represents 24% sequential growth from Q4 of that year. Together with the \$3.3 million in exclusivity payments recognized under our HCV agreement with AbbVie, total HCV-related revenues were \$5.5 million for the quarter.
- The revenue growth, along with prudent expense management, generated a slight profit for the first quarter.

Later in the call, I will provide an update on our HCV business, developments at DNA Genotek, the progress we have made on our new rapid Ebola test and the performance of our In-Home HIV test product.

So with that, I would like to turn the call over to Ron for his financial review.

**First Quarter 2015 Financial Results – Ron Spair**

Thanks Doug, and good afternoon everyone.

**Revenues – Ron Spair**

Our first quarter 2015 consolidated net revenues increased 15% to \$27.1 million, compared to \$23.5 million reported in 2014. Our consolidated product revenues of \$23.8 million increased 1% largely as a result of higher sales of our molecular collection systems, OraQuick® HCV and Intercept® products.

Other revenues were \$3.3 million in the current quarter and represent the recognition of exclusivity payments under the AbbVie agreement. We did not record similar revenues during the first quarter of 2014.

Our overall infectious disease testing revenues increased 4% in the first quarter of 2015, compared to the first quarter of 2014. Total HCV-related revenues, including the recognition of AbbVie exclusivity payments, increased 252% to \$5.5 million in the first quarter of 2015 compared to \$1.6 million in the first quarter of 2014.

HCV product revenues increased 39% to \$2.2 million in Q1 from \$1.6 million in the prior year. Sales of our OraQuick® HCV professional product in the domestic market increased 81% in the first quarter of 2015 to \$1.2 million from \$663,000 in the prior year. This increase is largely due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International sales of our HCV test in the first quarter of 2015 increased 8% to \$972,000 from \$896,000 in the same period last year, primarily due to higher sales into certain Asian markets as a result of regional expansion, partially offset by lower sales to Europe.

Domestic sales of our professional HIV product decreased 9% to \$6.0 million in the first quarter of 2015, compared to \$6.6 million in the first quarter of 2014. This decrease was the result of customers moving some of their testing to 4<sup>th</sup> generation automated HIV

immunoassays, price competition, and the timing of orders. We expect continued pressure on our professional HIV business for the foreseeable future.

International sales of our professional HIV product increased 70% to \$948,000 in Q1 compared to \$558,000 in the same period of last year. This change was primarily due to higher sales in Asia and Africa, partially offset by a decline in Europe.

During the current quarter, net sales of our OraQuick® In-Home HIV test decreased 20% to \$1.6 million compared to \$2.0 million in the first quarter of 2014. The decline can be attributed to our decision in the second half of 2014 to focus our marketing and promotional efforts at the retail outlet level and away from broad-based consumer advertising. As a result of the savings in advertising and promotional costs, this product line achieved profitability for the first quarter of 2015.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, increased 17% to \$6.7 million in the first quarter of 2015 compared to \$5.8 million in the first quarter of 2014. Commercial sales increased 32% as a result of the timing of orders placed from certain existing U.S. customers as well as incremental revenues from new customers. This increase was partially offset by a 7% decline in sales to academic customers due to variability in ordering patterns.

Substance abuse testing revenues increased 15% to \$2.1 million in the first quarter of 2015 compared to \$1.8 million in 2014. This increase is largely due to higher sales of our Intercept® device as a result of the recovery of customers previously lost to competition and improved domestic employment conditions.

First quarter 2015 cryosurgical revenues decreased 36% to \$2.5 million from \$4.0 million in the first quarter of 2014. Domestic sales of our professional product decreased 57% to \$661,000 in Q1 from \$1.5 million last year as a result of distributor consolidation and

competition from new private label brands. Sales of our OTC products in the international markets decreased 30% to \$1.5 million in the first quarter of 2015 compared to \$2.1 million in the first quarter of 2014 due to lower sales to both our European distributor, Reckitt Benckiser, and to our Latin American distributor, Genomma. The decline in sales to Europe was due to customer ordering patterns. The decline in sales to Latin America was due to ordering patterns and challenges faced by Genomma, including declining economic conditions in Argentina.

**Gross Margin – Ron Spair**

Gross margin for the first quarter of 2015 was 63% compared to 59% reported for the first quarter of 2014. The current quarter margin benefited primarily from the \$3.3 million of revenues recognized from our AbbVie relationship.

**Operating Expenses – Ron Spair**

Our consolidated operating expenses for the first quarter of 2015 decreased to \$17.3 million compared to \$19.5 million in the first quarter of 2014. This decrease was primarily due to lower promotional expenses associated with our OraQuick® In-Home HIV test, partially offset by higher R&D costs associated with the development of our fully-automated high-throughput drugs-of-abuse assays and higher legal fees.

**Net Income – Ron Spair**

From a bottom line perspective, we reported net income of \$113,000, or \$0.00 per share, for the first quarter of 2015, compared to a net loss of \$5.6 million, or \$0.10 per share, for the same period of 2014.

**Cash Flow from Operations and Liquidity – Ron Spair**

Turning briefly to our balance sheet and cash flow, we continue to maintain a solid cash and liquidity position. Our cash and short-term investment balance at March 31, 2015 was \$89.5 million compared to \$97.9 million at December 31, 2014. Cash used by operating activities in the first quarter of 2015 was \$6.6 million compared to \$7.7 million used in the first quarter of 2014.



**Second Quarter 2015 Consolidated Financial Guidance – Ron Spair**

Turning to guidance for the second quarter of 2015, we are projecting consolidated net revenues of approximately \$29.0 to \$29.5 million and consolidated net income per share of approximately breakeven to a penny per share for the quarter.

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

**Business Update – Doug Michels**

Thanks, Ron.

**OraQuick® HCV – Doug Michels**

Our HCV business continued to grow in Q1, with 24% sequential growth and 39% growth over the first quarter of 2014. We shipped product to over 460 customers during the first quarter and 86% of our revenues came from repeat customers. We also added 64 accounts during the quarter that had not previously ordered OraQuick® HCV tests from us.

As you know, a major focus of our HCV business has been, and will continue to be, our co-promotion agreement with AbbVie. We have been pursuing several major initiatives under this collaboration. As we have executed against each initiative, we have gained important knowledge and adjusted our strategy in response to evolving market conditions.

The market for HCV drug therapies has been developing very rapidly during the last year or so. As you might be aware, decisions today regarding which pharmaceutical products will be most accessible to patients are often influenced by insurance companies and other payors. In many cases, in an effort to reduce costs, payors negotiate discounted prices for drug therapies in exchange for giving those therapies a preferred or exclusive status on their formularies. Not surprisingly, the competition among HCV drug manufacturers to secure this favorable formulary status has been intense. This competition and the outcome of these negotiations influence where manufacturers focus their resources in order to provide the highest potential yield of new scripts for patients. These developments have affected our co-promotion efforts with AbbVie.

One example of this is in our largest initiative, directed to primary care and specialty physicians. Our approach under this initiative has been to combine detailing by the AbbVie sales force with our promotional activities through several large med-surg distributors and manufacturer representative organizations, or “MROs”. As a result of increased focus on its new HCV therapy, AbbVie reduced the physician detailing activities by its sales force for our HCV test during the first quarter. While not unexpected, this lower level of detailing will likely last through the second quarter as the competition for scripts settles out in the market. We anticipate AbbVie’s detailing of our product will resume to a more normal level sometime in Q3.

In the meantime, we have adjusted our approach by increasing the focus and efforts of our distributors and MROs to more effectively generate sales leads and customer interest within the physician market. We have also continued working to address work flow matters, reimbursement questions and other issues raised in the field that might delay or prevent a purchase decision by physician offices. We will continue working with these customers to accelerate the decision-making process.

A second initiative is directed at national and regional retail pharmacies and retail clinics. As indicated during our last call, we are planning to initiate several pilot programs with the goal of developing sustainable models for rapid HCV testing in retail outlets. One national pilot and a regional pilot will begin later this month and we expect a second national pilot to start shortly thereafter. The goal of these pilots is to develop a retail program that can be deployed on a national basis. Any revenue contribution from this initiative this year will be modest, but our expectation is that these pilots will be successful and that the retail market becomes a substantial contributor in the future.

A third initiative covers employer groups and was initially focused on the commercial long-haul trucking industry. This initiative has not developed the way we expected, in part, because of the competitive market conditions I just mentioned. As a result, we have terminated some of our industry-specific collaborations under this initiative, although we still believe truck drivers represent a potentially attractive target market.

In an effort to broaden our approach to employers beyond trucking, we are working with AbbVie to identify other work groups that may offer opportunities to promote both the use of our OraQuick® HCV test along with AbbVie's Patient Support Program. We believe a number of attractive employer groups will be identified through this screening process. Together with AbbVie, we are finalizing this review and we expect to focus our resources on new employer groups that are identified.

AbbVie and OraSure have also been looking at ways to expand our collaboration beyond the current agreement. One potential growth area is the public health market. Many public health customers are already using our rapid tests for both HIV and/or HCV, and this provides a great opportunity to promote either the initial or expanded use of our HCV test. Given the limited resources in public health jurisdictions, a program such as AbbVie's Patient Support Program is something that our public health customers find attractive. Based on initial discussions with over 100 public health customers, interest is quite high for combining the use of our rapid HCV test with AbbVie's Patient Support Program.

Overall, both OraSure and AbbVie remain committed to our co-promotion agreement. We continue to believe it represents significant opportunities for both companies and we intend to devote the focus and resources needed to maximize the success of this important collaboration.

**Molecular Collection Systems – Doug Michels**

Another area I will touch on is our molecular collection systems business. As Ron explained, DNA Genotek continued its run of strong quarterly performances with 17% revenue growth over the prior year quarter.

DNA Genotek's revenues were split 60% commercial customers and 40% academic, which is consistent with past performance. During the first quarter, all of the growth occurred in DNA Genotek's commercial business while academic sales declined compared to the prior year.

One particular strength on the commercial side is in the area of pharmacogenomics, which uses genetic testing to study a person's expected response to a particular drug treatment. Our pharmacogenomics customers accounted for double digit growth during the first quarter compared to 2014.

Another growing part of DNA Genotek's business is in the area of reproduction genetics and breast cancer screening. We now believe DNA Genotek is the primary DNA collection device supplier for a majority of the leading companies in both areas. As you may know, the breast cancer screening market in particular is growing rapidly and we expect this part of the market to continue to deliver strong results in future periods.

During the first quarter, DNA Genotek was successful with 23andMe, its largest commercial customer, in obtaining FDA 510(k) clearance for the Oragene® • DX saliva collection product. 23andMe uses this device to collect samples from its customers. Our 510(k) clinical study confirmed that the Oragene® • DX device is reliable and easy to use for consumers at home, while also providing high quality DNA samples for processing in a laboratory.

As you may recall, DNA Genotek is also pursuing 510(k) clearance of its ORACollect® device. I am happy to report that this clinical work is progressing well. We expect to submit our 510(k) application to the FDA during the third quarter of this year.

Finally, as you know DNA Genotek is based in Canada. The strengthening U.S. dollar relative to the Canadian dollar delivered both expense savings and foreign currency exchange gains during the first quarter, all of which positively contributed to our consolidated bottom line results.

### **Rapid Ebola Test – Doug Michels**

As discussed on prior calls, our newest product in development is a rapid Ebola antigen test on our OraQuick® platform. During the past several months we have been working diligently to fully develop, fund and deploy this new product.

During the first quarter, we locked the design of a prototype device that appears to deliver analytical performance similar to PCR tests when evaluated on stored samples from infected patients. During the first quarter, we also recognized revenues from the initial sales of this product to the CDC for investigational use in Africa. The data generated from this field testing, along with other clinical and non-clinical studies we will perform, is expected to be used in an application to obtain Emergency Use Authorization from the FDA during the next several months. We also intend to use this data for similar approvals internationally.

We have also continued discussions with governmental agencies in an effort to obtain external funding for our development efforts. Good progress has been made and we are optimistic that we will be able to share some positive news on this funding effort in the very near future.

On a parallel path, we have engaged with many governmental and other entities to identify and secure one or more purchase commitments for the product once approved for use. As explained previously, our ability to successfully obtain development funding along with substantial and sustainable product purchase commitments is critical to the future of this product.

### **HIV OTC – Doug Michels**

A final area I will briefly touch upon is our OraQuick® In-Home HIV test business. Because we have implemented a more cost effective promotional strategy, I am happy to report that this product line achieved profitability during the first quarter of 2015 and we

expect this product to be profitable for the year. We also intend to continue to look for ways to grow this business in a profitable manner. Along these lines, we are pleased to announce that we recently received CE mark approval for our OraQuick® In-Home HIV test. We are continuing to assess various go-to-market strategies in certain European markets, but will only launch in these additional markets if we can demonstrate a pathway to profitable expansion.

**Conclusion**

So, as you heard today there is no shortage of exciting growth opportunities before the Company. We believe we have the right strategy and resources in place to achieve our goals and objectives for the year. And we look forward to updating you on our progress during our next call.

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, including the OraQuick® In-Home HIV test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in CDC or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure's stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation;

changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2014, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this call, and we undertake no duty to update these statements.