
**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 6, 2014

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 August 6, 2014, OraSure Technologies, Inc. (the “Company”) issued a press release announcing its consolidated financial results for the quarter ended June 30, 2014, and providing financial guidance for the third quarter of 2014. 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 6, 2014, 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, 2014, provided financial guidance for the third quarter of 2014 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 August 6, 2014, announcing consolidated financial results of OraSure Technologies, Inc. for the quarter ended June 30, 2014, and providing financial guidance for the third quarter of 2014.
99.2	Prepared Remarks of Douglas A. Michels and Ronald H. Spair for OraSure Technologies, Inc. Second Quarter 2014 Analyst/Investor Conference Call Held August 6, 2014.

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: August 6, 2014

ORASURE TECHNOLOGIES, INC.

By: /s/ Jack E. Jerrett

Jack E. Jerrett
Senior Vice President, General Counsel
and Secretary

Index to Exhibits

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OraSure Technologies, Inc.

Company Contact:

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Chief Financial Officer
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www.orasure.com

OraSure Announces 2014 Second Quarter Financial Results

BETHLEHEM, PA – August 6, 2014 – (Globe Newswire) – OraSure Technologies, Inc. (NASDAQ: OSUR), a market leader in oral fluid diagnostics, today announced its consolidated financial results for the three and six months ended June 30, 2014.

Financial Highlights

- Consolidated net revenues for the second quarter of 2014 were \$26.4 million, an 8% increase from the comparable quarter of 2013. Consolidated net revenues for the six months ended June 30, 2014 were \$49.9 million, a 10% increase from the comparable period of 2013. These increases were primarily due to higher sales of the Company's OraQuick® HCV test, higher revenues from the Company's molecular collection systems subsidiary, DNA Genotek ("DNAG"), higher sales of the Company's cryosurgical systems products, and higher licensing and product development revenues.
- Net revenues for the Company's OraQuick® rapid HCV test were \$2.2 million and \$3.8 million for the second quarter and first six months of 2014, respectively, an increase of 134% from each of the comparable 2013 periods. This growth reflects increasing demand for the product in both the domestic and international markets.
- Net revenues generated by DNAG during the second quarter of 2014 were \$4.9 million, a 5% increase from the comparable period in 2013. DNAG net revenues during the six months ended June 30, 2014 were \$10.7 million, a 24% increase from

the comparable period in 2013. The increase in the quarter was the result of higher sales to academic customers while the increase for the six month period was the result of higher sales to both commercial and academic customers.

- Net cryosurgical systems revenues in the second quarter of 2014 were \$4.9 million, an 18% increase over the second quarter of 2013. This increase was primarily due to higher sales in the international over-the-counter (“OTC”) market. Net cryosurgical systems revenues for the six months ended June 30, 2014 were \$8.9 million, a 22% increase over the comparable period of 2013. This increase was primarily due to higher sales in both the U.S. professional market and the international OTC market.
- Licensing and product development revenues were \$775,000 for both the quarter and six months ended June 30, 2014, and represent the recognition of payments under the company’s HCV collaboration with AbbVie. In exchange for exclusive promotion rights and certain services provided by the Company, the agreement with AbbVie provides for payments totaling up to \$75.0 million over the life of the agreement, which runs through December 31, 2019. The first such payment of \$15.0 million required under the agreement was received in July 2014. Licensing and product development revenues in 2013 represent royalties paid on domestic outsales of Merck’s OTC cryosurgical wart removal product.
- Consolidated net income for the second quarter of 2014 was \$2.5 million, or \$0.04 per share on a fully diluted basis, which compares to a net loss of \$5.3 million, or \$0.10 per share, for the second quarter of 2013. Consolidated net loss for the six months ended June 30, 2014 was \$3.1 million, or \$0.06 per share, which compares to a net loss of \$15.5 million, or \$0.28 per share, for the comparable period of 2013. The improvement in the Company’s bottom line for the quarter and six month period resulted primarily from the inclusion of a \$5.5 million payment due under the terms of the termination of a drug assay collaboration with Roche Diagnostics, the higher revenues in each period and lower promotional costs for the OraQuick® In-Home HIV Test.

“We are pleased with the Company’s financial performance for the second quarter and first six months of the year,” said Douglas A. Michels, President and CEO of OraSure Technologies. “Sales of our OraQuick® HCV test were up nicely and our molecular collection systems business showed continued growth from the year ago periods. Significant effort is now being directed towards the execution of our HCV collaboration with AbbVie. We expect this collaboration will contribute substantially to our business in future periods.”

Financial Results

Consolidated net product revenues for the second quarter of 2014 increased 6%, primarily as a result of higher sales of the Company's OraQuick® HCV, cryosurgical systems, and molecular collection systems products. These increases were partially offset by lower domestic sales of the OraQuick® professional HIV product, OraQuick® In-Home HIV test and insurance risk assessment products.

Consolidated net product revenues for the six month period ended June 30, 2014 increased 9% primarily as a result of higher sales of the Company's OraQuick® HCV, molecular collection systems and cryosurgical systems products. These increases were partially offset by lower domestic sales of the OraQuick® professional HIV product and lower substance abuse and insurance risk assessment product sales.

Consolidated licensing and product development revenues for the second quarter and first six months of 2014 were \$775,000. Consolidated licensing and product development revenues for the second quarter and first six months of 2013 were \$274,000 and \$476,000, respectively. Licensing and product development revenues in 2014 represent the recognition of payments under the Company's HCV collaboration with AbbVie. Licensing and product development revenues in 2013 represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product.

Consolidated gross margin for the three and six months ended June 30, 2014 was 61% and 60%, respectively. Consolidated gross margin for the three and six months ended June 30, 2013 was 60% and 58%, respectively. Gross margin for the current quarter and six month period primarily benefited from a more favorable product mix due to higher margin DNAG sales.

Consolidated operating expenses decreased to \$13.5 million during the second quarter of 2014 compared to \$20.1 million in the comparable period of 2013. For the six months ended June 30, 2014, consolidated operating expenses were \$33.1 million, a decrease from the \$42.7 million reported for the six months ended June 30, 2013. The decrease for the second quarter of 2014 was primarily due to the inclusion of the \$5.5 million Roche payment and lower promotional expenses associated with the Company's OraQuick® In-Home HIV test. These latter expenses totaled \$3.0 million during the current quarter, compared to \$5.4 million in the second quarter of 2013. The decrease for the six month period of 2014 was primarily due to the \$5.5 million Roche payment, lower promotional expenses associated with the Company's OraQuick® In-Home HIV test and decreased research and development expenses due to lower clinical trial and staffing costs. Promotional expenses for the OraQuick® In-Home test were \$7.6 million and \$12.3 million for the first six months of 2014 and 2013, respectively. General and administrative expenses in the both the current and six month periods increased due to higher legal, staffing and consulting costs.

For the three and six months ended June 30, 2014, the Company recorded Canadian income tax benefits of \$174,000 and \$43,000, respectively. For the three and six months ended June 30, 2013, the Company recorded Canadian income tax benefits of \$249,000 and \$659,000, respectively. The tax benefits were recorded as a result of certain Canadian research and development and investment tax credits and DNAG's loss before income taxes.

The Company's cash and short-term investment balance totaled \$80.3 million at June 30, 2014 compared to \$93.2 million in cash at December 31, 2013. Working capital was \$101.1 million at June 30, 2014 compared to \$100.6 million at December 31, 2013. For the six months ended June 30, 2014, the Company used \$10.4 million to fund operations.

Third Quarter 2014 Outlook

The Company expects consolidated net revenues to range from \$27.0 to \$27.5 million and is projecting a consolidated net loss of approximately \$0.04 to \$0.05 per share for the third quarter of 2014.

Condensed Consolidated Financial Data

(In thousands, except per-share data)

Unaudited

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Results of Operations				
Net revenues	\$26,401	\$24,337	\$49,938	\$ 45,501
Cost of products sold	10,385	9,838	19,995	18,973
Gross profit	16,016	14,499	29,943	26,528
Operating expenses:				
Research and development	2,771	2,693	5,252	6,050
Sales and marketing	10,272	12,369	21,612	26,243
General and administrative	5,976	5,013	11,700	10,400
Gain on contract termination settlement	(5,500)	—	(5,500)	—
Total operating expenses	13,519	20,075	33,064	42,693
Operating income (loss)	2,497	(5,576)	(3,121)	(16,165)
Other income (expense)	(142)	42	(24)	(5)
Income (loss) before income taxes	2,355	(5,534)	(3,145)	(16,170)
Income tax benefit	(174)	(249)	(43)	(659)
Net income (loss)	<u>\$ 2,529</u>	<u>\$ (5,285)</u>	<u>\$ (3,102)</u>	<u>\$ (15,511)</u>
Earnings (loss) per share:				
Basic	<u>\$ 0.05</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.28)</u>
Diluted	<u>\$ 0.04</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.28)</u>
Weighted average shares:				
Basic	<u>55,907</u>	<u>55,559</u>	<u>55,846</u>	<u>55,504</u>
Diluted	<u>57,243</u>	<u>55,559</u>	<u>55,846</u>	<u>55,504</u>

Summary of Revenues by Market and Product (Unaudited)

	Three Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2014	2013	% Change	2014	2013
Market					
Infectious disease testing	\$12,668	\$11,966	6%	47%	49%
Substance abuse testing	2,208	2,113	4	8	9
Cryosurgical systems	4,920	4,177	18	19	17
Molecular collection systems	4,896	4,654	5	19	19
Insurance risk assessment	934	1,153	(19)	4	5
Net product revenues	<u>25,626</u>	<u>24,063</u>	<u>6</u>	<u>97</u>	<u>99</u>
Licensing and product development	775	274	183	3	1
Net revenues	<u>\$26,401</u>	<u>\$24,337</u>	<u>8%</u>	<u>100%</u>	<u>100%</u>

	Six Months Ended June 30,				
	Dollars			Percentage of Total Net Revenues	
	2014	2013	% Change	2014	2013
Market					
Infectious disease testing	\$23,732	\$22,654	5%	47%	50%
Substance abuse testing	4,038	4,362	(7)	8	9
Cryosurgical systems	8,887	7,261	22	18	16
Molecular collection systems	10,655	8,586	24	21	19
Insurance risk assessment	1,851	2,162	(14)	4	5
Net product revenues	<u>49,163</u>	<u>45,025</u>	<u>9</u>	<u>98</u>	<u>99</u>
Licensing and product development	775	476	63	2	1
Net revenues	<u>\$49,938</u>	<u>\$45,501</u>	<u>10%</u>	<u>100%</u>	<u>100%</u>

	Three Months Ended June 30,			Six Months Ended June 30,		
	2014	2013	% Change	2014	2013	% Change
OraQuick® Revenues						
Domestic HIV	\$ 7,720	\$ 8,088	(5)%	\$14,339	\$15,761	(9)%
International HIV	848	745	14	1,405	1,300	8
Domestic HIV OTC	1,669	1,993	(16)	3,622	3,435	5
Net HIV revenues	10,237	10,826	(5)	19,366	20,496	(6)
Domestic HCV	1,221	690	77	1,884	1,119	68
International HCV	974	247	294	1,870	486	285
Net HCV revenues	2,195	937	134	3,754	1,605	134
Net OraQuick® revenues	\$12,432	\$11,763	6%	\$23,120	\$22,101	5%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2014	2013	% Change	2014	2013	% Change
Intercept® Revenues						
Domestic	\$1,616	\$1,342	20%	\$2,866	\$2,745	4%
International	33	98	(66)	73	356	(79)
Net Intercept® revenues	\$1,649	\$1,440	15%	\$2,939	\$3,101	(5)%

	Three Months Ended June 30,			Six Months Ended June 30,		
	2014	2013	% Change	2014	2013	% Change
Cryosurgical Systems Revenues						
Domestic professional	\$1,469	\$1,497	(2)%	\$3,011	\$2,388	26%
International professional	229	257	(11)	538	605	(11)
International over-the-counter	3,222	2,423	33	5,338	4,268	25
Net cryosurgical systems revenues	\$4,920	\$4,177	18%	\$8,887	\$7,261	22%

Condensed Consolidated Balance Sheets (Unaudited)

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
<u>Assets</u>		
Cash	\$ 75,832	\$ 93,191
Short-term investments	4,437	—
Accounts receivable, net	14,152	12,957
Inventories	13,229	11,444
Other current assets	8,155	1,983
Property and equipment, net	18,471	17,933
Intangible assets, net	20,443	22,226
Goodwill	23,674	23,782
Other non-current assets	1,172	729
Total assets	<u>\$ 179,565</u>	<u>\$ 184,245</u>
<u>Liabilities and Stockholders' Equity</u>		
Accounts payable	\$ 4,647	\$ 4,834
Deferred revenue	694	1,119
Accrued expenses	9,366	13,032
Other non-current liabilities	1,157	677
Deferred income taxes	3,381	3,437
Stockholders' equity	160,320	161,146
Total liabilities and stockholders' equity	<u>\$ 179,565</u>	<u>\$ 184,245</u>

Additional Financial Data (Unaudited)	Six months ended	
	June 30,	
	2014	2013
Capital expenditures	\$ 1,988	\$1,092
Depreciation and amortization	\$ 3,108	\$3,221
Stock based compensation	\$ 2,869	\$2,835
Cash used in operating activities	\$10,397	\$9,278

Conference Call

The Company will host a conference call and audio webcast to discuss the Company's 2014 second quarter financial results, certain business developments and financial guidance for the third quarter of 2014, 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 #74668640 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 13, 2014, by dialing 855-859-2056 (Domestic) or 404-537-3406 (International) and entering the Conference ID #74668640.

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. The Company sells the OraQuick® In-Home HIV Test, the first and only rapid HIV test approved by the U.S. Food and Drug Administration for sale to the consumer over-the-counter market in the U.S. In addition, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. 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, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on the Company, please visit www.orasure.com

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 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 collaboration 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, 2013, 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.

2014 Second Quarter

Analyst/Investor Conference Call

August 6, 2014

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.

Our financial performance for the second quarter was strong, as we met our guidance on the top line and exceeded it on the bottom line.

- Consolidated net revenues for the quarter were \$26.4 million, an 8% increase from Q2 of 2013.
- Our HCV business had a particularly good quarter with sales growth of 134% from the prior year period. Our molecular collection systems revenues rose 5% over the prior year despite the absence of revenue from DNA Genotek’s largest customer.
- We are also pleased to report a consolidated net profit of \$2.5 million, primarily due to a \$5.5 million payment we received in connection with the termination of our drug assay collaboration with Roche Diagnostics.

In June, we announced a significant new agreement with AbbVie for the co-promotion of our OraQuick® HCV rapid antibody test. The Company granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain U.S. markets and in exchange for these rights and certain other services will receive up to \$75.0 million in payments over the term of the agreement which runs through December 31, 2019. In addition, the Company is

eligible to receive annual fees based on performance. These fees can range from \$3.5 million to \$55.5 million per year and will be based on the number of patients that test positive with our OraQuick® HCV test and enroll into a patient support program sponsored by AbbVie.

Since the announcement, we have received the first payment from AbbVie under that agreement and recognized a portion of that payment as revenue during the second quarter. In addition, we have made great progress in preparing for the launch of our co-promotion activities, which get underway in earnest this month. I will provide additional detail on these activities later in the call.

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

Second Quarter 2014 Financial Results – Ron Spair

Thanks Doug, and good afternoon everyone.

Revenues – Ron Spair

Our second quarter 2014 consolidated net revenues were \$26.4 million, compared to \$24.3 million reported in 2013. Our consolidated product revenues increased 6% as a result of higher sales of our OraQuick® HCV, cryosurgical systems, and molecular collection systems products. These increases were partially offset by lower domestic sales of our OraQuick® professional HIV product, OraQuick® In-Home HIV test and insurance risk assessment products. Licensing and product development revenues were \$775,000 in the current quarter compared to \$274,000 in 2013.

Our overall infectious disease testing revenues increased 6% to \$12.7 million in the second quarter of 2014, compared to \$12.0 million in the second quarter of 2013. Aggregate sales of our OraQuick® HCV professional product in both the domestic and international markets increased 134%. Higher demand in the

domestic market among new and existing customers contributed to the increase in sales of our HCV test in Q2 to \$1.2 million from \$690,000 in the prior year. International sales of our HCV test in the second quarter of 2014 increased to \$974,000 from \$247,000 in the same period last year primarily due to sales in support of a significant testing program with an international NGO. We expect sales to this NGO will be at a much reduced rate in Q3 and Q4.

Domestic sales of our professional HIV product decreased to \$7.7 million in the second quarter of 2014 from \$8.1 million in the second quarter of 2013. This decrease was the result of continued pressure on government budgets, some customer migration to automated 4th generation immunoassay HIV tests as recommended under new testing guidelines issued by the CDC, and changes in customer ordering patterns. We expect these headwinds to continue for the foreseeable future.

During the current quarter, net sales of our OraQuick[®] In-Home HIV test were \$1.7 million compared to \$2.0 million in the second quarter of 2013. Net revenues for these periods were not recorded using the same revenue recognition policy and are not readily comparable. Revenues in the current quarter were recognized upon shipment to the distribution channels while revenues in the second quarter of 2013 were recognized upon consummation of a sale to the end user. To better evaluate the performance of this product as compared to the year ago period, we can look at the number of units purchased by consumers. Based on available point of sale data, unit consumption declined by approximately 1% in the second quarter which we believe was due to a decrease in broad-based media advertising.

Second quarter 2014 cryosurgical revenues increased 18% to \$4.9 million from \$4.2 million in the second quarter of 2013, primarily as a result of higher OTC sales in Europe and Latin America. OTC sales increased to \$3.2 million in the second quarter of 2014 from \$2.4 million in the second quarter of 2013 due to

higher sales to our European distributor as a result of the launch of our product into new geographic territories, continued market penetration, and the ordering patterns of our Latin American distributor.

Our molecular collection systems revenues, primarily representing sales of the Oragene® product line, increased to \$4.9 million in the second quarter of 2014 compared to \$4.7 million in 2013. This 5% increase was the result of higher sales in the academic market due to the timing of orders placed by our distributors and studies performed by several larger academic customers. Commercial sales remained flat despite the fact that the current quarter did not include any sales to DNAG's largest commercial customer. The prior year quarter included approximately \$1.7 million in sales to this customer.

Licensing and product development revenues were \$775,000 in the second quarter of 2014 and represent the amortization of revenues from AbbVie under our HCV collaboration agreement. In July, we received the first payment of \$15.0 million as required under the agreement. Second quarter 2013 licensing and product development revenues were \$274,000 and represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product.

Gross Margin – Ron Spair

Gross margin for the quarter ended June 30, 2014 was 61% compared to 60% reported for the quarter ended June 30, 2013. The current quarter margin benefited primarily from a more favorable product mix driven largely by the increase in DNAG sales to higher margin customers.

Operating Expenses – Ron Spair

Our consolidated operating expenses for the second quarter of 2014 decreased to \$13.5 million during the second quarter of 2014 compared to \$20.1 million in the second quarter of 2013. Current quarter expenses were reduced by a \$5.5 million

settlement payment from Roche Diagnostic under the terms of the termination of our oral fluid assay collaboration agreement. Also contributing to the decrease in operating expenses was lower advertising and promotional spending related to our OraQuick® In-Home HIV test. Our advertising and promotional expenses for our OTC HIV test were \$3.0 million in the second quarter of 2014, compared to \$5.4 million spent in the second quarter of 2013. This decrease was partially offset by an increase in general and administrative expense due to higher legal, staffing, and consulting costs.

Net Income – Ron Spair

From a bottom line perspective, we reported net income of \$2.5 million, or \$0.04 per share on a fully-diluted basis, for the second quarter of 2014, compared to a net loss of \$5.3 million, or \$0.10 per share, for the same period of 2013.

Cash Flow from Operations and Liquidity – Ron Spair

Turning briefly to our balance sheet and cash flow, our cash and short-term investment balance at June 30, 2014 was \$80.3 million compared to \$93.2 million in cash at December 31, 2013. Cash used in operating activities in the second quarter of 2014 was \$2.7 million compared to \$1.6 million used in the second quarter of 2013.

Third Quarter 2014 Consolidated Financial Guidance – Ron Spair

Turning to guidance for the third quarter of 2014, we are projecting consolidated net revenues of approximately \$27.0 to \$27.5 million and a consolidated net loss per share of approximately \$0.04 to \$0.05 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

As you know, there have been many positive developments in our OraQuick® HCV business.

The most recent was the execution of a major agreement under which AbbVie and OraSure will co-promote our OraQuick® HCV rapid test in the United States. A redacted copy of this agreement was filed today with the SEC along with our second quarter Form 10-Q. We encourage you to review this document.

Under our agreement with AbbVie, we will be focusing our co-promotion efforts on several specific markets in the U.S. As you might expect, a significant amount of work has already begun under this agreement.

The largest market segment consists of primary care and specialty physicians. AbbVie has agreed to detail our HCV test into this market segment and we will be targeting in excess of 10,000 physicians. Training of the AbbVie representatives on our product has already occurred, and product detailing started this week. To support these efforts, AbbVie will be launching its patient support program later this month, to assist patients who screen positive for HCV. This program will help patients understand the implications of their diagnosis and steps they can take to address their infection.

Our manufacturing representative organizations (MROs) and our Infectious Disease sales team are coordinating with their AbbVie counterparts on all aspects of this co-promotion. We are providing product samples to qualified accounts along with personal and web-based training on the use of our product for physicians. We are also implementing a co-payment assistance program to help reduce the costs for commercially insured and uninsured patients. Additionally, we are offering a telephone hotline for comprehensive customer support. Product sales driven by the co-promotion effort will be handled through our distributors and our direct sales team.

A second market segment targeted for co-promotion consists of employers or employer groups that are at high risk for hepatitis C and desire to make HCV testing available to their employees. Our initial focus is in the transportation industry and specifically on commercial truck drivers, who are five times more likely to have hepatitis C than other Americans according to a study published in the American Journal of Public Health. We have been working closely with the Healthy Truckers Association of America, or HTAA, which is a trade association focused on improving the health and wellness of professional truck drivers. With HTAA's assistance, OraSure and AbbVie will work to increase awareness about hepatitis and the benefits of our OraQuick® rapid HCV test. We will be specifically promoting the use of our test in physician offices, health clinics and in retail pharmacies where truckers receive their health care as well as at driving schools where newly-hired drivers are required to take and pass a physical exam. In addition, we will be promoting our test for use at health events sponsored by HTAA where truckers can take advantage of a variety of health and wellness services. We will be kicking off these efforts with the trucking industry in the third week of August with a major testing event organized by HTAA at the Great American Trucking Show in Dallas, Texas.

Another major market segment we are working on consists of national retail pharmacies and retail clinics. As you know, an increasing number of vaccines and diagnostic tests are becoming available to consumers through local retail pharmacy outlets. OraSure and AbbVie are in discussions with several major retail pharmacies and clinics and are making good progress on this initiative.

As you might suspect, the market segments covered by our collaboration with AbbVie are substantial. A great deal of work is required to build awareness, promote our test and implement the various support services that are needed, including product training, co-payment assistance and patient support. Although we are working to implement this collaboration as quickly as possible, we will likely not see any significant impact from these efforts until next year.

Apart from all the work being done on the AbbVie collaboration, we continue to drive revenue growth in our existing HCV business. The \$2.2 million in revenues reported for the second quarter was a record and included a record \$1.2 million of revenues here in the U.S. We shipped product to over 500 customers during the quarter, with 82% of our shipments being delivered to repeat customers. We also added over 90 new customers during the quarter.

As previously discussed, a number of states have passed laws that require doctors to offer hepatitis C testing as a routine part of healthcare provided to baby boomers. New York was the first state to pass such a law earlier this year. Legislation is now pending in at least eight other states and, recently, Colorado, Massachusetts and Connecticut passed laws requiring the offering of HCV testing to baby boomers.

In addition, in June the Centers for Medicare and Medicaid Services, or CMS, posted a final national coverage determination indicating that Medicare will now cover hepatitis C screening for persons at high risk for contracting the disease and for individuals that do not meet the high risk definition but fall within the baby boomer generation because they were born from 1945 through 1965. The CMS determination is consistent with recent recommendations from the U.S. Preventive Services Task Force which assigned a "B" rating for this type of preventive service.

So as we plan for the future, we are very optimistic about this part of our business. We expect continued growth, especially here in the U.S., to be driven by the continued positive market developments affecting HCV testing and from our HCV collaboration with AbbVie. I look forward to providing you with updates on this part of the business in future calls.

HIV-OTC – Doug Michels

Turning now to our HIV-OTC business . . .

As Ron explained, the lower net sales of our In-Home test during the second quarter are not really comparable to the year ago period because of the change in our revenue recognition policy last year. An alternative measure is to compare actual shipments of product to retailers, which increased 54% in Q2 versus the comparable quarter of 2013. Retail outsales to customers, as measured in the accounts for which we receive point-of-sales data, declined 1% in the current quarter compared to 2013 and declined 5% versus the first quarter of the year. These declines in retail sales were not surprising given our recent decision to reduce promotional spending for this business.

As you may recall, we previously announced that we would implement a new promotional strategy, which is focused on more cost-effective methods of building awareness and consumer adoption at the retail store level. Early in the second quarter, we began reducing the more expensive broad-based consumer advertising and as of August 1 we had ceased this form of advertising, except for some residual or “make good” media owed to us by our media vendors. As predicted, we are seeing the initial impact of this reduction on our growth, with average weekly retail outsales in April and May down 9% and 8%, respectively, versus the prior month. However, the average weekly sales grew in June by 4% over May and remained roughly at that same level in July.

We may continue to see some sequential declines in August and September outsales as we fully implement our new promotional strategy. Our expectation is that these sales will eventually plateau and then resume growth in the fourth quarter, albeit at lower levels, driven by the more tactical retail trade level programs we are implementing. On this front, we are working with retailers on select pricing promotions, in-store media and public relations tied to key moments of momentum for the category to drive awareness and purchase activation.

On prior calls we have noted the high proportion of stores that stock the product behind the pharmacy counter. As a result, we have undertaken a survey of pharmacists to identify the best tools to overcome this barrier and facilitate education and purchase at the retail level. Results indicate high product awareness (75%), high acceptance and a desire for materials and coupons to be distributed to consumers to motivate actual purchases. We will begin implementing these tools in the fourth quarter.

As a result of all of our changed strategy, our promotional costs will drop to \$1 million or less starting in the third quarter. Our goal and expectation is to achieve profitability for this product in 2015.

On the international front, we are pleased to announce the submission of an application for CE Mark approval, a requirement for marketing the product in Europe. We are also evaluating several additional foreign markets where we see good potential for regulatory and commercial success. Our U.S. experience, and particularly the challenges we have seen in building this new brand, will be factored into our commercial assessments of potential new international markets.

As previously explained, our OraQuick® In-Home HIV test remains an important part of our business, and we remain committed to the profitable growth of this product line. We still believe in the long-term potential for the product, but we recognize that it is going to take time to build awareness and stimulate further customer acceptance. Going forward, we will continue to align spending with revenues and drive this product line towards profitability.

Molecular Collection Systems – Doug Michels

Another area I want to address is our molecular collection systems business.

DNA Genotek continued its strong performance during the second quarter by delivering \$4.9 million in revenue. This represents growth of 5% over 2013. Sales for the first six months of 2014 to both the academic and commercial markets were up a combined 24% when compared to the first half of last year. I believe this performance is outstanding, especially when you consider that DNA Genotek received over \$1 million less revenue from 23andMe in the first half of this year compared to last year. In fact, revenues from all other customers increased 63% during the first six months of this year compared to 2013.

During the quarter, DNA Genotek also made significant progress in its efforts to commercialize new products. In June, DNA Genotek began shipping early prototypes of sample management products for research related to gut microbiome and tuberculosis. These prototypes represent two new, long-term market opportunities that we are developing. Gut microbiome studies are gaining momentum and our new sample management product will enable researchers to improve their results through better sample collection, storage and handling. In tuberculosis, we are again in the early commercialization stages of a product that is expected to improve the workflow for testing sputum samples for TB. We are excited about these new opportunities and believe they represent a logical extension of our current molecular collection business.

Substance Abuse Testing – Doug Michels

A final area I want to address is our substance abuse testing business. The primary reason we reported a net profit for the second quarter was the \$5.5 million payment required in connection with the termination of our drug assay collaboration with Roche Diagnostics. A pre-condition for this payment was the submission of a final purchase order by the end of June, for the high-throughput assays previously developed under this collaboration. We were able to submit this final order because of the good progress we have made under our new drug assay collaboration with Thermo Fisher Scientific.

As previously discussed, we signed an agreement with Thermo Fisher in November 2013 that will enable us to provide our lab customers with fully-automated oral fluid assays that can be used on existing clinical chemistry automated analyzers to process samples collected with a new version of our Intercept® collector. These assays, along with improvements in our new Intercept® device, will enable us to better serve the needs of our drug testing customers.

Conclusion

So in conclusion, we have high expectations for our business, particularly our OraQuick® HCV test and our molecular collection systems segment. We are on track to deliver record results in 2014 and our efforts in the second half of this year will be instrumental in laying the groundwork for a successful 2015.

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 collaboration 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, 2013, 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 Report, and we undertake no duty to update these statements.